LEXSEE 309 F. SUPP. 2D 531

In re: REZULIN PRODUCTS LIABILITY LITIGATION (MDL No. 1348); This Document Relates to: All Cases

MASTER FILE 00 Civ. 2843 (LAK)

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

309 F. Supp. 2d 531; 2004 U.S. Dist. LEXIS 5197; CCH Prod. Liab. Rep. P16,930

March 15, 2004, Decided

SUBSEQUENT HISTORY: Complaint dismissed at, in part *Wong v. Pfizer, Inc. (In re Rezulin Prods. Liab. Litig.), 2004 U.S. Dist. LEXIS 7692 (S.D.N.Y., Apr. 28, 2004)*

PRIOR HISTORY: *In re Rezulin Prods. Liab. Litig., 2004 U.S. Dist. LEXIS 3104 (S.D.N.Y., Feb. 27, 2004)*

DISPOSITION: [**1] Defendants' motion in limine granted in part and denied in part..

COUNSEL: Mark P. Robinson, Jr., Kevin F. Calcagnie, ROBINSON, CALCAGNIE & ROBINSON. Irving H. Greines, Cynthia E. Tobisman, GREINES, MARTIN, STEIN & RICHLAND, LLP. Ramon Rossi Lopez, LOPEZ HODES RESTAINO MILMAN & SKIKOS. Chris Tisi, ASCHRAFT & GEREL, Attorneys for Plaintiffs.

David Klingsberg, Steven Glickstein, Maris Veidemanis, Wendy S. Dowse, KAYE SCHOLER LLP, Attorneys for Defendants.

JUDGES: Lewis A. Kaplan, United States District Judge.

OPINION BY: Lewis A. Kaplan

OPINION

[*538] **MEMORANDUM OPINION**

(Corrected)

LEWIS A. KAPLAN, *District Judge.*

Among the antecedents of our modern jury trial was wager of law, or compurgation, a form of trial by ordeal. The accused found a number of people and then took a solemn oath that he or she was innocent. The "companions, or 'compurgators' as they were called, then swore that the oath which he [or she] had taken was clean. In other words, the court called upon the accused to produce a specified number of people . . . who were prepared to swear that in their opinion his [or her] oath was trustworthy. * * * They did not swear to the facts of the case, [**2] but merely to their judgment that the accused is a credible person." [1]

1 THEODORE F. T. PLUCKNETT, A CONCISE HISTORY OF THE COMMON LAW 115 (5th ed. 1956) (footnote omitted).

A practice reminiscent of wager of law has become fashionable among some well-financed litigants -- the engagement of "expert" witnesses whose intended role is more to argue the client's cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit. These "experts" thus are loosely analogous to compurgators, also known as oath helpers, in that they lend their credentials and reputations to the party who calls them without bringing much if any relevant knowledge to bear on the facts actually at issue. This case exemplifies the fashion to some extent, as the Plaintiffs' Executive Committee has engaged a number of "expert" witnesses to perform roles which, in greater or lesser degree, meet this description.

Defendant Warner-Lambert [**3] Company and affiliates move *in limine* to exclude certain proposed testimony of a number of [*539] plaintiffs' experts on issues other than silent liver injury, which is the subject of another motion. They object to proposed testimony of plaintiffs' "experts" regarding (1) what constitutes ethical behavior for a company, (2) the motive, intent, and state of mind of actors including Warner-Lambert, Glaxo-Wellcome, U.S. Food and Drug Administration ("FDA") employees, and the authors of scientific articles, (3) Warner-Lambert's alleged suppression of research, (4) foreign regulatory experience with respect to Rezulin [troglitazone] including a "history" of regulatory actions, (5) FDA procedures and regulations and Warner-Lambert's alleged failure to provide adequate information to the FDA about Rezulin, (6) Warner-Lambert's alleged failure adequately to protect patients who participated in the Rezulin clinical trials, (7) what other physicians understood about Rezulin, its benefits and risks, (8) decisions made by physicians who prescribed Rezulin, (9) a duty to warn patients (as well as alleged failure to warn patients); (10) Rezulin's efficacy and its risk-benefit ratio; and (11) one [**4] expert's reliance on certain spreadsheets created by a consultant for the defendants.

I. *Legal Framework:* Daubert v. Merrell Dow Pharmaceuticals Inc. *and Federal Rule of Evidence 702.*

A. *General Background*

The standard governing a district court's determination whether to admit scientific or other expert testimony is familiar. *Federal Rule of Evidence 702* provides:

> "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

It incorporates principles established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* [2] in which the Supreme Court charged trial courts with a gatekeeping role to "ensure that any and all scientific [**5] testimony or evidence admitted is not only relevant, but reliable." [3]

2 *Daubert, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993).*

3 *Id. at 589.*

In *Daubert,* the Supreme Court set forth the procedures a trial court is to follow in ruling on expert testimony. The trial court must determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." [4] The Court explained further that this requires "a preliminary assessment of whether the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue" -- in essence, whether it is reliable. [5] The proponent of expert testimony must demonstrate admissibility by a preponderance of proof. [6] The *Daubert* Court stressed that the inquiry concerning reliability is "a flexible one" and set forth a list of four nonexclusive factors to consider: (1) whether the expert's theory "can be (and [**6] has been) tested"; (2) whether the theory "has been subjected to peer review and publication;" (3) the "known or potential [*540] rate of error"; and (4) whether the theory has "'general acceptance.'" [7]

4 *Id. at 592.*

5 *Id. at 592-93.*

6 *Id. at 592 n.10.*

7 *Id. at 593-94.*

The Court elaborated upon *Daubert* in *Kumho Tire Co. v. Carmichael,* [8] where it held that Daubert's general gatekeeping obligation "applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." [9] Ultimately, the objective of *Daubert* is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." [10]

8 *526 U.S. 137, 143 L. Ed. 2d 238, 119 S. Ct. 1167 (1999).*

[**7]

9 *Id. at 141.*

10 *Id. at 152.*

In undertaking this inquiry, a district court must focus on the "principles and methodology" employed by the expert, not on the conclusions reached. [11] Nevertheless, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there simply is too great an analytical gap between the data and the opinion proffered." [12]

11 *Daubert, 509 U.S. at 594-95.*

12 *General Electic Co. v. Joiner, 522 U.S. 136, 146, 139 L. Ed. 2d 508, 118 S. Ct. 512 (1993).*

In 2000, *Rule 702* was amended in light of *Daubert* to require that "(1) the testimony [be] based upon sufficient facts or data, (2) the testimony [be] the product of reliable principles and methods, and (3) the witness [have] [**8] applied the principles and methods reliably to the facts of the case." The Advisory Committee Notes explain that the amendment was intended to affirm Daubert's designation of the trial court as gatekeeper and "provide[] some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony." [13] The standards set forth in *Rule 702* were not intended to displace the nonexclusive list of factors set forth by the Supreme Court in *Daubert,* however.

13 *Fed. R. Evid. 702* Committee Note (2000).

One of the fundamental requirements of *Rule 702* is that the proposed testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." This helpfulness requirement is "akin to the relevance requirement of *Rule 401*, which is applicable to all proffered evidence[,] [but] . . . goes beyond mere relevance . . . because it also requires expert testimony to have a valid connection to the pertinent inquiry." [14] The *Daubert* Court referred [**9] to this as "'fit,'" noting that "*Rule 702*'s 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." [15] Finally, *Rule 702* requires also a finding that the proposed witness be qualified by virtue of specialized knowledge, skill, experience, training, or education.

14 4 JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN'S FEDERAL EVIDENCE § 702.03[1] (Joseph M. McLaughlin ed., 2d ed. 1997).

15 *Id. at 591*; *see also In re Paoli R.R. Yard PCB Litig., 916 F.2d 829, 857 (3d Cir. 1990)* (helpfulness standard requires more than "'bare logical relevance'").

Recognizing that the application of the foregoing principles, "no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations," the Supreme Court in [*541] *Daubert* nevertheless reasoned that this "is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding [**10] but for the particularized resolution of legal disputes." [16]

16 *Daubert, 509 U.S. at 597.*

B. *Specific Considerations.*

Certain principles that are especially pertinent to the task at hand flow from the requirement that expert testimony be "scientific, technical, or other specialized knowledge." First, the requirement of "knowledge" guards against the admission of subjective or speculative opinions. [17] Second, in requiring that expert testimony be directed to "scientific, technical or specialized" knowledge, *Rule 702* ensures that expert witnesses will not testify about "lay matters which a jury is capable of understanding and deciding without the expert's help." [18] In other words, experts should not be permitted to "supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence." [19] Examples of "expert" testimony that courts have excluded on this basis include factual narratives [20] and interpretations of conduct or views as to the [**11] motivation of parties. [21]

17 *Id. at 590* ("the word 'knowledge' connotes more than subjective belief or unsupported speculation.")

18 *Andrews v. Metro North Commuter Railroad Co., 882 F.2d 705, 708 (2d Cir. 1989)* (citations omitted); *accord LinkCo, Inc. v. Fujitsu Ltd.,* 2002 U.S. Dist. LEXIS 12975, No. 00 Civ. 7242, 2002 WL 1585551 (S.D.N.Y. July 16, 2002), at *1; *Taylor v. Evans,* 1997 U.S. Dist. LEXIS 3907, No. 94 Civ. 8425, 1997 WL 154010, at *2 (S.D.N.Y. April 1, 1997).

19 *Primavera Familienstifung v. Askin, 130 F. Supp. 2d 450, 527, amended on reconsideration*

on other grounds, 137 F. Supp.2d 438 (S.D.N.Y. 2001).

20 *See, e.g., Taylor,* 1997 U.S. Dist. LEXIS 3907, 1997 WL 154010, at *2.

21 *See, e.g. Lippe v. Bairnco Corp., 288 B.R. 678, 688 (S.D.N.Y. 2003).*

Likewise, in deciding whether the proposed testimony will be helpful to the factfinder, courts in this Circuit analyze the testimony to determine whether it "'usurp[s] [**12] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it.'" [22] Thus, although an expert may give an opinion to help the jury decide an issue in the case, he or she may not tell the jury what result to reach [23] or communicate "a legal standard -- explicit or implicit -- to the jury." [24] This principle requires the exclusion of testimony that states a legal conclusion, although factual conclusions on an ultimate issue to be decided by the jury are permissible. [25]

22 *United States v. Lumpkin, 192 F.3d 280, 290 (2d Cir. 1999)* (quoting *United States v. Duncan, 42 F.3d 97, 101 (2d Cir. 1994)*) (quoting *United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir. 1991).*

23 *U.S. v. Duncan, 42 F.3d at 100* ("When an expert undertakes to tell the jury what result to reach, this does not *aid* the jury in making a decision, but rather attempts to substitute the expert's judgment for the jury's.") (emphasis in original)

24 *Hygh v. Jacobs, 961 F.2d 359, 364 (2d Cir. 1992)* (trial court improperly admitted testimony defining legal phrase "deadly physical force" in manner inconsistent with applicable definition in New York Penal Law);*United States v. Scop, 846 F.2d 135, 140, rev'd in part on reh'g on other grounds, 856 F.2d 5 (2d Cir. 1988)* (excluding expert's repeated use of statutory and regulatory language indicating guilt); see also *LinkCo, Inc. v. Fujitsu, Ltd.,* 2002 U.S. Dist. LEXIS 12975, No. 00 Civ. 7242, 2002 WL 1585551, (S.D.N.Y. July 16, 2002), at *2 (excluding expert testimony that "it is my expert opinion that [defendant] misappropriated trade secrets that originated at [the plaintiff's].")

[**13]

25 *Duncan, 42 F.3d at 101*; *Bilzerian, 926 F.2d at 1294*

The rule follows the Advisory Committee's view that *Rules 701, 702and 403* act as limitations on the use of experts as oath-helpers under *Rule 704*: "Under *Rules 701and 702*, opinions must be helpful to the trier of fact, and *Rule 403* provides for exclusion of evidence which wastes time. These provisions afford ample assurances *against the admission of opinions which would merely tell the jury what result to reach,* somewhat in manner of the oath-helpers of an earlier day." *FED. R. EV. 704* advisory committee's note (West 2003) (emphasis added).

[*542] Against this background, the Court now turns to its analysis of the challenged testimony.

II. Testimony Regarding Ethics.

The reports of two of plaintiffs' proposed experts indicate that they intend to testify, at least in part, that Warner-Lambert, in their opinions, acted in an unethical manner, especially with respect to its presentation of, or reaction to, Rezulin clinical data and the conduct of Rezulin [**14] clinical trials. Two other experts gave such testimony in their depositions. [26] Defendants seek to preclude all such testimony by plaintiffs' experts. They argue that the opinions are (1) unreliable because purely speculative; (2) unhelpful to the fact-finder because irrelevant in a case where liability is premised on legal, not ethical, standards, and (3) likely to prejudice and confuse fact-finders concerning the pertinent legal standards. Plaintiffs rejoin that the proffered testimony is reliable and establishes an industry standard that is relevant to the issues in the case.

26 Dr. Bell stated in his deposition, "The ethical way it should have been presented when it was seen [that] there was an enzyme problem, there usually is not with drugs, was that this should then have been looked at more closely and divided up . . . So I did think this is relevant in this situation that an ethical pharmaceutical company would have presented the data in a different way when, in fact, it was realized there were enzyme elevations." Bell Dep. 146-48. He rendered other similar commentary couched in terms of what constitutes "reasonable and prudent" pharmaceutical conduct in research. *Id.* at 328-32, 340-42. He stated also that he uses the

terms "ethical" and "reasonable" interchangeably. *Id.* at 341-42. (This use of the word "ethical" is not to be confused with its use in the phrase "ethical pharmaceutical," which refers to a prescription drug.)

In discussing a document written by another, Dr. Day stated, "I agree with this analysis and believe it to be unethical to conduct studies upon human beings without first fully studying the effects of a drug upon cultured cells and, then, animals." Day Report P15.

Dr. Kronmal's report expressed views concerning the ethical obligations and duties of pharmaceutical companies, stating "if any indication is present that the investigational drug may be causing serious or potentially adverse events, it is the responsibility of the company to bring this to the attention of the FDA. Anything less than full and complete reporting of any 'signal' that the drug might be dangerous would be unreasonable and unethical behavior that is not standard industry practice." Kronmal Report P24; *see also id.* PP26, 37(c). His deposition testimony is replete with similar judgments. Kronmal Dep. 58-71.

Dr. Furberg's report states that he intends to "comment[] on how the Company adhered to . . . the ethical obligations of practicing physicians, research subjects and regular patients." Furberg Rep. P8. It states that "research sponsors have ethical obligations to the study investigators and to their respective Institutional Review Boards (IRBs) that are similar to their obligations to the FDA" and that "it is my opinion that through a series of deceptive practices, the Company violated accepted standards of clinical trial practice, regulatory guidelines, obligations, trust and codes of ethics. The company directly or indirectly deceived the major parties involved in medical research and patient care . . ." *Id.* at PP15, 34. Dr. Furberg said that by "ethical" he means "what is an expected obligation on the part of a responsible sponsor." Furberg Dep. 109-110.

[**15] The opinions of plaintiffs' witnesses, however distinguished these individuals may be as physicians and scientists, concerning the ethical obligations of pharmaceutical [*543] companies and whether the defendants' conduct was ethical are inadmissible for the following reasons.

A. *Reliability Under Rule 702 and Daubert.*

Three of plaintiffs' four witnesses -- Drs. Day, Bell and Kronmal -- have admitted that their opinions concerning purported ethical standards are based on their personal, subjective views. [27] These opinions therefore do not meet the core requirement of *Rule 702* that expert testimony rest on "knowledge," a term that "connotes more than subjective belief or unsupported speculation." [28]

27 At his deposition, Dr. Bell admitted that he was not "an expert on ethics" but that he is entitled to, and holds, a "personal opinion" about "the behavior of pharmaceutical companies." Bell Dep. 147-48. Plaintiffs' attempt to recast Dr. Bell's challenged testimony as relating to something other than ethics (*viz.* reasonableness) does not alter the effect of Dr. Bell's admission that his opinions in this area -- however labeled -- are speculative.

Dr. Day's opinion on the ethics of pharmaceutical testing is, by its terms, a personal belief. Day Report P15 (*"I . . . believe* it to be unethical . . .") (emphasis supplied).

Dr. Kronmal testified that he knows of no ethical guidelines that apply to the formatting or presentation of data in a New Drug Application and that his view on the ethical obligations of pharmaceutical companies in that regard is based on a personal opinion and his own "subjective views." Kronmal Dep. 67-70. He testified also that there is "no standard methodology for ethics." *Id.* at 68. Dr. Kronmal's experience in working on clinical trials and consulting for pharmaceutical companies does not transform his admittedly subjective views on ethical standards into appropriate subjects of expert testimony. *See* Pl. Opp. 7-8.

[**16]

28 *Daubert, 509 U.S. at 590. See also Mancuso v. Consol. Edison of New York, 967 F. Supp. 1437, 1441 (S.D.N.Y. 1997)* (expert testimony that is speculative or conjectural is inadmissible) (citations omitted).

Such speculative testimony, contrary to plaintiffs' argument, cannot serve as the predicate for any purported industry ethical standard. [29] Even if expert testimony on the ordinary practices of a profession or trade were appropriate "to enable the jury to evaluate the conduct of the parties against the standards of ordinary practice in the industry," [30] it still must comport with the reliability and helpfulness requirements of *Rule 702*. At their core, however, the witnesses' opinions regarding ethical standards for reporting or analyzing clinical trial data or conducting clinical trials articulate nothing save for the principle that research sponsors should be honest. [31] Even if charitably viewed as a "standard," the testimony nevertheless is "so vague as to be unhelpful to a fact-finder." [32]

29 *See Grdinich v. Bradlees, 187 F.R.D. 77, 81 (S.D.N.Y 1999)* (excluding expert opinion allegedly based on industry standards as unsupported speculation where only basis for standard were general "common-sense" guidelines.)

To similar effect is *Bush v. Michelin,* cited by the plaintiffs, which stands for the proposition that a court will scrutinize evidence of industry standards to ensure that it is "sufficient to suggest an industry standard." *963 F. Supp. 1436, 1446 (W. D. Ky. 1996)* (reserving decision on admissibility pending court's review). Similarly unhelpful to the plaintiffs is *Ray v. Wal-Mart Stores, Inc., 120 F.3d 882 (8th Cir. 1997)*, where the reliability of the industry standards evidence was presumed and no claim was raised -- as it is here -- that the expert's opinions were purely subjective.

[**17]

30 *Marx & Co., Inc. v. Diners' Club, Inc., 550 F.2d 505, 509-510 (2d Cir. 1977)* (citing VII WIGMORE ON EVIDENCE § 1949, at 66 (3d ed. 1940)).

31 *See* note 25.

32 *Primavera Familienstifung v. Askin, 130 F. Supp. 2d 450, 529, amended on reconsideration in part, 137 F. Supp. 2d 438 (S.D.N.Y. 2001)* (Sweet, J.) (excluding as overly vague proposed industry standard testimony that "broker dealers are expected to act with the highest integrity.")

The fact that Dr. Furberg has three decades of personal experience with clinical trials, Furberg Dep. 28-29, does not render him qualified to opine about purported ethical standards when all that he says is that study sponsors should be honest and that this is "what reasonable people would think," including his peers in the field of clinical research. *Id.* at 29-30. As Judge Sweet noted in *Primavera,* judges should not be "deceived by the assertions of experts who offer credentials rather than analysis." *Id.* (citing *Minasian v. Standard Chartered Bank, PLC, 109 F.3d 1212, 1216 (7th Cir. 1997).*

[**18] Plaintiffs press the notion that "there is no authority proscribing opinions which [*544] are personal, a label which can be attached to any expert's testimony." [33] The claim, at best, is frivolous word play. Its clear implication is that courts should permit "experts" to tender purely subjective views in the guise of expert opinions. This would border on the absurd.

33 Pl. Opp. 58.

B. *Relevance Under Rule 702 and* Daubert.

Even assuming that the ethics testimony were based on a reliable foundation, it would not assist the fact-finder in determining any factual dispute in this case. The principal issues here are whether the defendants breached their legal duties to the plaintiffs in the manufacturing, labeling and marketing of Rezulin and, if so, whether any such breaches were proximate causes of injury. While the defendants may be liable in the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to [**19] these lawsuits.

Ethics testimony similar to that proposed here was excluded as irrelevant in *Diet Drugs,* a pharmaceutical products liability proceeding analogous in some ways to this MDL. [34] There, the court excluded the opinions of a "clinical medical ethics" expert because the testimony was "at best, only marginally relevant to [the manufacturer's] conduct in the manufacturing and marketing of diet drugs," and the "pertinent issues in this litigation are the obligations of a pharmaceutical company in testing, surveying and labeling medications." [35] Those same obligations, not what is ethical, are the central issues in this case, and the proffered ethics testimony is "at best, only marginally relevant." [36]

34 *In re Diet Drugs Prods. Liab. Litig. , 2001 U.S. Dist. LEXIS 1174, No. MDL 1203, 2001 WL 454586, at *9 (E.D. Pa. Feb. 1, 2001).*

35 *2001 U.S. Dist. LEXIS 1174, [WL] at *9.*

36 See also *DiBella v. Hopkins*, 2002 U.S. Dist. LEXIS 20856, No. 01 Civ. 11779, 2002 WL 31427362 (S.D.N.Y. Oct. 30, 2002) (opinions of "business ethics" expert regarding parties' business dealings inadmissible in commercial dispute; evidence was unhelpful "because the dispute here is not over what is ethical. Rather, the dispute is over what happened.").

Plaintiffs' argument that the challenged opinions are relevant to "illuminate the applicable negligence standard" disregards the principle that expert opinions that would encroach on the role of the trial judge in instructing the jury as to the applicable law are inadmissible. *United States v. Lumpkin, 192 F.3d 280, 289* (quoting *United States v. Duncan, 42 F.3d 97, 101 (2d Cir. 1994)* (quoting *United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir. 1991)*).

Plaintiffs' reliance on *Andrade v. Columbia Med. Center, 996 F. Supp. 617 (E.D. Tex. 1998)*, is misguided. In that malpractice case, the court held that expert testimony about the ethical duties of doctors and other health care providers was relevant to the standard of care on the plaintiffs' claims of ordinary and gross negligence. The *Andrade* decision concluded, without citation, that the ethics testimony would help the jury understand the pertinent standard of care and whether the defendants deviated from it. To the extent that the case turns implicitly on duties that the Hippocratic oath imposes on medical professionals, it is inapplicable to this case, which involves the legal duties of pharmaceutical companies. To the extent that the case is not so limited, the Court declines to follow it. Other precedents relied upon by the plaintiffs are inapposite. *See Ray v. Wal-Mart, supra* (relevance of the expert testimony not challenged); *The Post Office v. Portec, Inc., 913 F.2d 802, 807 (10th Cir. 1990), vacated and remanded on other grounds, 499 U.S. 915, 113 L. Ed. 2d 235, 111 S. Ct. 1299 (1991)* (party waived objection to relevance of expert testimony on code of ethical standards for engineers).

[**20] [*545] C. *Federal Rule of Evidence 403.*

Even assuming that the proposed ethics testimony were reliable and marginally relevant under *Rule 702*, it would be likely unfairly to prejudice and confuse the trier by introducing the "experts'" opinions and rhetoric concerning ethics as alternative and improper grounds for decision on bases other than the pertinent legal standards. 37 Accordingly, plaintiffs are precluded from offering any testimony, including that cited in the margin, concerning ethical standards and the application of ethical standards to the alleged conduct of the defendants and others.

37 The risk that the legal standard of care and the purported "ethical" standards will be blurred is particularly evident in the cases of Drs. Furberg and Bell, who use the terms "ethical" and "reasonable" interchangeably. *See* Furberg Dep. 109-10; Bell Dep. 146-48, 328-32, 340-42.

III. Motive, Intent, and State of Mind Testimony

Several of plaintiffs' proposed experts [**21] have rendered reports articulating, and/or testified in depositions to, opinions concerning the motive, intent and state of mind of Warner-Lambert and others. 38 Defendants object that the testimony (1) is unreliable speculation because the witnesses lack relevant qualifications, and (2) would invade the province of the jury. 39 [*546] Plaintiffs rejoin that the witnesses are qualified, and the opinions are helpful under *Rule 702* and proper under *Rule 704*. The Court concludes that the testimony is inadmissible.

38 Dr. Furberg addressed Warner-Lambert's intent and motive in its medical research and patient care, as well as deceptive practices in which Warner-Lambert allegedly engaged. Furberg Rep. PP31, 34, 35, 43; Furberg Dep. 158. For example, he said that Warner-Lambert "decided to focus on the incomplete and inaccurate approval data and to minimize the troubling post-approval data." Furberg Rep. P43.

Dr. Bell opined on the motive and intent of Warner-Lambert, the FDA, and Glaxo-Wellcome as well as individual witnesses. Bell Report PP32, 38, 39-42; Bell Dep. 182-3.

Dr. Gale's report states: "While it is possible to believe that abnormalities of liver enzymes

might slip unremarked through the normal process of drug surveillance, the fact that 20 patients had to be taken off the drug for this reason (one trialist in 125) makes it highly improbable that the company was unaware of this issue prior to marketing. Failing to notice it would constitute negligence; if known, failing to report it and to recommend liver screening would carry more serious implications." Gale Report P64. It goes on to say that "it seems clear that Glaxo-Wellcome put the safety of patients before all considerations, and that others involved did not." *Id.* P83. He asserted in his deposition that Warner-Lambert was motivated by profit: "If you have a highly profitable product on the market, I think there would be a natural reluctance to withdraw it prematurely. This may have been a factor in the way in which information concerning the safety of this product reached the ears of the regulators and physicians concerned." Gale Dep. 244-45. He then speculated regarding the motivation of the FDA in making decisions in approving or removing drugs, *id.* at 162, and opined that Glaxo-Wellcome had altruistic motives when it withdrew Rezulin from the UK market." Gale Report P83.

Dr. Gale discussed also the intent of authors of a medical article in the *New England Journal of Medicine,* speculating as to why they included a reference to twenty specific patients. "If Dr. Whitcomb found it necessary to write and restate and, indeed, considerably amplify this information 15 months later in the New England Journal, it implies that Dr. Whitcomb did not believe that American physicians were, in general, aware of the advice that had been issued." Gale Dep. 223. He further stated, ". . . I think one reads any scientific article with some understanding of the intention of the authors." *Id.*

Dr. Smith accused Warner-Lambert of "suppressing scientific inquiry for the stated purpose of downplaying the hepatotoxic effects of TGZ in the published literature." Smith Report P41.

[**22]

39 Defendants argue also that evidence of Warner-Lambert's profit motive is categorically irrelevant because "profit motive is the foundation of our economic system" and thus cannot serve as a predicate for tort liability. This sweeping argument is frivolous and deserves no further comment. Similarly inapposite is plaintiffs' lengthy rebuttal, which relies on cases dealing with the relevance of *non-expert* evidence.

First, the opinions of these witnesses on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise. [40] The *Taylor* court aptly described similar testimony as "musings as to defendants' motivations [that] would not be admissible if given by any witness -- lay or expert." [41] Furthermore, plaintiffs' experts propose improperly to assume the role of advocates for the plaintiffs' case by arguing as to the intent or motives underlying the conduct of Warner-Lambert or others, a transgression that has resulted in the exclusion of "expert" testimony as to the "real motive" behind certain [**23] business transactions. [42]

40 Dr. Gale admitted that his testimony about Warner-Lambert's profit motive was an "inference" unrelated to any scientific analysis of the efficacy or benefits as Rezulin. Gale Dep. at 244-245. He admitted also that he had no idea whether Warner-Lambert earned any profits from the sale of Rezulin. *Id.* at 244. He also acknowledged that he was not an expert in corporate intent, just someone who is "able to draw inferences," *id.* at 245, the same (he also conceded) as non-endocrinologists and lawyers. *Id.* at 245. He admitted too that he has no factual or scientific basis for his views regarding the intent, motive or state of mind of Glaxo-Wellcome, the FDA and the authors of the March 1998 letter to the *NEJM. Id.* at 162, 202, 223, 224. In the face of these admissions, it is irrelevant that Dr. Gale may have published a peer-reviewed article in the *Lancet* on the subject of profits driving pharmaceutical companies in general and Rezulin in particular. Regardless of this article, Dr. Gale has admitted that the testimony he proposes to give in *this* case is based on a series of inferences with no basis in fact or scientific method.

Likewise, neither Drs. Smith, Bell, nor Furberg claimed any particular expertise on the

intent, motive or state of mind of corporations or regulatory agencies. Thus Dr. Bell cannot provide an expert opinion as to the motives, for example, that underlay Warner-Lambert's conduct with respect to clinical studies or Glaxo's motivation for taking Rezulin off the market in Europe. Nor can Dr. Furberg speculate that Warner-Lambert "chose" to allegedly give incomplete information with respect to Rezulin label. And so on.

[**24]

41 *Taylor v. Evans,* 1997 U.S. Dist. LEXIS 3907, No. 94 Civ. 8425, 1997 WL 154010, at *2 (S.D.N.Y. April 1, 1997) (excluded expert opinions that "Quite frankly, the ECS caseworker removed the Plaintiff's two children because she did not like her attitude and was unwilling to admit any wrongdoing" and "Mr. Evans was annoyed that Plaintiff did not admit to causing the injuries . . ." and "Mr. Evans did not want to hear Plaintiffs' story."). *See also DePaepe v. General Motors Corp., 141 F.3d 715, 720 (7th Cir. 1998)* (trial court erred by allowing expert to testify as to why General Motors had reduced the amount of padding in its automobile sun visors; expert "lacked any scientific basis for an opinion about the motives of GM's designers.")

42 *Lippe v. Bairnco, 288 B.R. 678, 688 (S.D.N.Y. 2000).*

The testimony is improper also because it describes "lay matters which a jury is capable of understanding and deciding without the expert's help." [43] Dr. Bell's proposed testimony illustrates the point. At times he merely repeated facts or opinions stated by other potential [**25] witnesses or in documents produced in discovery, as with his reiteration of Dr. Misbin's view as to what the FDA might have done with different information. Elsewhere, he drew simple inferences from documents produced [*547] in discovery, as when he said he "knows for sure" that Glaxo took Rezulin off the market for safety reasons because "the chairman of the company" allegedly wrote this in a letter. [44] Similar repetitions of facts and speculative inferences about intent appear throughout the challenged testimony. [45]

43 *Andrews v. Metro North Commuter R. Co., 882 F.2d at 708.*

44 Bell Report P38; Bell Dep. 182-83.

45 Even plaintiffs essentially concede that the testimony consists of "lay matter." For instance, while denying that Dr. Smith opines about intent or motive -- which is untrue, *see* note 38 *supra* -- they say that his testimony simply describes "the facts and conditions from which the jury could infer defendant's motivation in stifling research." Pl. Opp. 33.

[**26] Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony. As the *Diet Drugs* court stated in excluding testimony that the pharmaceutical defendant's conduct with respect to labeling was motivated by its desire to increase profits, "the question of intent is a classic jury question and not one for the experts." [46]

46 *In Re Diet Drugs,* 2000 U.S. Dist. LEXIS 9037, No. MDL 1203, 2000 WL 876900, at *9 (E. D. Pa. June 20, 2000). See also *In Re Diet Drugs, 2001 U.S. Dist. LEXIS 1174, No. MDL 1203, 2001 WL 454586, *2 (E.D. Pa. Feb. 1, 2001)* (excluding testimony of expert regarding "what the corporate intent of [defendant] and/or what beliefs of FDA officials were on matters upon which they spoke or acted.")

Dr. Gale's opinion that Warner-Lambert's conduct with respect to clinical trial data potentially constituted "negligence" or "something more serious" [47] is excluded for the additional reason that it impermissibly embraces a legal conclusion. [48] Such testimony "usurp[s] . . . [**27] the role of the trial judge in instructing the jury as to the applicable law [and] the role of the jury in applying that law to the facts before it." [49]

47 Gale Report P64.

48 *See, e.g. United States v. Scop, 846 F.2d 135, 139, modified, 856 F.2d 5 (2d. Cir. 1988)* (reversed conviction based on improper expert testimony where witness tracked exact language of securities statutes and regulations which the defendant had allegedly violated and used judicially defined terms such as "manipulation," "scheme to defraud" and "fraud" in opining on the defendant's conduct).

49 *United States v. Lumpkin, 192 F.3d at 289.*

Accordingly, plaintiffs are precluded from offering expert opinion evidence, including that cited in the margin, of the alleged motive, intent or state of mind of defendants or others.

IV. *Testimony about FDA Procedures and Regulations and Disclosure of Facts to the FDA*

Most of plaintiffs' challenged witnesses have [**28] given opinions on FDA procedures, regulations, and standards as well as statements that Warner-Lambert failed adequately to disclose material facts about Rezulin to the FDA. [50] The Court notes [*548] also that all of these challenged opinions to varying degrees recite facts, or agree with opinions, stated in the deposition of Dr. Misbin, [51] including his view that the FDA would not have approved Rezulin monotherapy had it been aware of certain liver injury data from the clinical trials. [52]

50 Dr. Avorn testified that the FDA would have delayed the approval of Rezulin if it had been aware of the potential for, or possibility of, severe hepatotoxocity. Avorn Dep. 311. His report commented that "[i]It further indicates that the manufacturer was in possession of important information on hepatotoxicity that it did not reveal in a complete and timely manner to the Food and Drug Administration or to prescribing physicians." Avorn Report 1.

Dr. Bell's report offers extensive commentary on FDA labeling regulations and criticisms of Warner-Lambert's adherence to those regulations with respect to the Rezulin label. The report is replete also with comments to the effect that Warner-Lambert misled the FDA by providing incomplete or erroneous information. Bell Report PP29-51. For example, it states that "following the submission of a '4-month Safety Update' on May 23, 1998, containing erroneous and misleading information with respect to liver toxicity seen in the clinical trials, the FDA approved the Supplemental New Drug Applications for first-line monotherapy and for combination use with sulfonylureas." *Id.* P31. *See also id.* PP34, 37, 41, 45.

Dr. Bonkovsky expressed the view that, "My impression, from reading the L.A. Times article, is that Warner-Lambert was not entirely forthcoming in reporting the possible hepatotoxicity of Rezulin." Bonkovsky Dep. 95. "And I'll bet the FDA, in retrospect, wishes they never approved it." *Id.* 73.

Dr. Furberg's report and deposition expressed the view that Warner-Lambert submitted erroneous and incomplete safety reports to the FDA and to the FDA Advisory Committee and that this allegedly inadequate disclosure "had consequences for the drug's approval." Furberg Report PP35, 39; Furberg Dep. 95. Dr. Furberg stated also that "the Company failed to comply with the established FDA guideline for reporting Efficacy and Safety Summary Data and with many of the fundamental principles that form the basis for medical research. It deceived investigators, health care providers, study subjects and regular patients regarding the unacceptable risks of serious liver function abnormalities and damages." Furberg Report P46. In addition, he commented on what he called "noteworthy" deposition testimony of Dr. Misbin to the effect that the FDA would not have approved Rezulin monotherapy had it been aware of the true rate of liver injury from the clinical trials. Furberg Rep. P39.

Dr. Gale offered opinions touching on regulatory matters including comments on FDA requirements for drug studies and aspects of the FDA's approval process for Rezulin, such as whether Rezulin was placed on a "fast track" approval, or noting that the transcript of a Rezulin Advisory Committee meeting included a comment about liver safety. Gale Rep. PP34-36, 56, 57.

Dr. Julie opined that Rezulin probably would not have been "fast-tracked" or approved for first-line therapy had Warner-Lambert presented information to the FDA in a different format. Julie Dep. (7/29/02) 28-30.

Dr. Kronmal discussed FDA standards for the presentation of clinical data and the duties of a pharmaceutical company under those procedures, also offering his view that FDA standards are "minimal." Kronmal Report PP23-25.

[**29]

51 Dr. Misbin was an FDA medical officer who participated personally in the review and approval of the Rezulin NDA. He is the only witness that the FDA has made available for a deposition in this case.

52 *See, e.g.,* Misbin (12/21/02) Dep. 124-195,

223-224. The references to Dr. Misbin's testimony are explicitly highlighted in plaintiffs' opposition papers. *See, e.g.,* Pl. Opp. 47, 53 (Drs. Furberg and Julie). Approving references to Dr. Misbin appear throughout the experts' deposition transcripts.

Warner-Lambert seeks to preclude these opinions on the grounds that they are (1) speculative and unreliable because none of the witnesses has expertise in FDA procedures and regulations, and (2) fraud-on-the-FDA evidence which, it claims, is inadmissible under *Buckman Co. v. Plaintiffs' Legal Committee.* [53] Plaintiffs rejoin that regulatory expertise is unnecessary because the proffered testimony -- as recharacterized by them -- does not speak to regulatory standards, but merely establishes that Warner-Lambert's disclosures of clinical trial data to the FDA were inadequate [**30] and misleading. Plaintiffs claim also that FDA regulations are "minimum" standards. Plaintiffs oppose defendants' *Buckman* argument as an unwarranted extension of that precedent.

53 *531 U.S. 341, 148 L. Ed. 2d 854, 121 S. Ct. 1012 (2001)* (state fraud-on-the-FDA claims pre-empted by federal law).

A. *Reliability.*

Despite the plaintiffs' claim to the contrary, portions of the challenged testimony do unequivocally discuss, and evaluate Warner-Lambert's conduct against, FDA standards. [54] Plaintiffs do not dispute [*549] that extensive regulations govern the form and content of clinical data submissions to the FDA [55] or that the experts here in question disavow any expertise on the subject. [56] The proffered opinions on FDA standards and regulations therefore are inherently unreliable. Further, there is no foundation for the view that FDA regulations are "minimal standards," for the witnesses cannot characterize -- as "minimal" or otherwise -- regulations that they do not know or understand in the first place. Plaintiffs' experts [**31] are unqualified also to testify about the *facts* of Warner-Lambert's disclosures to the FDA because they lack first-hand knowledge. [57]

54 Dr. Bell, for instance, said regarding an FDA regulation that "it is my understanding that proof of causation of these events need not be established in order for a company to add a warning to physicians." Bell Report P45. Dr. Bell clearly asserted also that Warner-Lambert did not comply with FDA reporting guidelines. *Id.* P46. For other examples of opinions that obviously touch on FDA regulations, see note 50.

55 *See, e.g., 21 C.F.R. §§ 312.47.*

56 Dr. Avorn is unfamiliar with the FDA-required format for submission of liver data in the Rezulin NDA. Avorn Dep. 142.

Dr. Bell admitted he is "not an expert in U.S. regulatory affairs" and that he did not intend to give expert opinions on the subject. Bell Dep. 22. Despite his disavowal, Dr. Bell did opine on FDA regulations (*see* Bell Report PP29-51), but admitted that his views on the subject are "personal," rather than "scientific," opinions. Bell Dep. 97.

Dr. Bonkovsky conceded that he was not "knowledgeable" or an "expert" in the FDA regulatory process. Bonkovsky Dep. (4/13/01) 129-30. This may account for why some of his opinions were based on an "impression" or a "bet." *See* note 50.

Dr. Gale said that he did not intend to give regulatory testimony and admitted that "the design of studies for the regulatory process" is "beyond [his] area of expertise." Gale Dep. 152. He admitted also that he lacks expertise on "the details and the minutiae of FDA procedures, what constitutes fast track, accelerated or whatever approvals are details on which I would not care to express a detailed opinion." *Id.* at 186.

Plaintiffs have offered no pertinent evidence that Drs. Furberg and Julie are qualified to opine on regulatory matters.

Dr. Kronmal admitted that he knows nothing about FDA regulations governing the content and format of NDA submissions -- the subject of his opinions. Kronmal Dep. 16, 20, 55, 96, 100. Also, although not dispositive, plaintiffs' counsel himself stated during Dr. Kronmal's deposition that he is "not an FDA expert." *Id.* at 104.

[**32]

57 For example, Dr. Kronmal's deposition is replete with admissions that he lacks first-hand knowledge of the facts underlying defendants' presentation of NDA data. *See* Kronmal Dep. 61-62, 98, 103-04, 178. Other witnesses gave

similar testimony. None, therefore, may opine about the facts or adequacy of the defendants' presentation of Rezulin clinical data to the FDA or, as with Dr. Bonkovsky, regarding the factual accuracy of information in the Rezulin label.

Plaintiffs' reliance on *Diet Drugs* is inapposite. There, the court allowed the testimony of a former FDA medical officer on the factual discrepancies between what was known to the defendant drug company and the contents of the drug labeling because he was *"undoubtedly qualified to do so in light of his experience as an FDA officer." See In re Diet Drugs,* 2000 U.S. Dist. LEXIS 9037, 2000 WL 876900, at *18. (emphasis added). None of the proposed expert witnesses in this case has the same, or analogous, qualifications.

Accordingly, plaintiffs' experts that are subject to this aspect of the motion -- Drs. Avorn, Bell, Bonkovsky, Gale, [**33] Furberg, Julie and Kronmal -- are not qualified to render opinions describing or interpreting FDA regulations, or commenting on Warner-Lambert's adherence to those regulations.

B. *Helpfulness under Rule 702.*

To the extent that the challenged testimony relates, as plaintiffs contend, to the factual accuracy of Warner-Lambert's clinical data submissions to the FDA, it constitutes lay matter that the fact-finder can understand without the assistance of experts, regardless of much experience these witnesses have with clinical trials. [58] [*550] Dr. Avorn's testimony illustrates the point. His view that Warner-Lambert failed to disclose information to the FDA boils down to a contention that Warner-Lambert "buried" certain lab results in an Appendix to the Rezulin NDA. [59] This opinion does not implicate Dr. Avorn's expertise in pharmacoepidemiology. It is a simple inference drawn from his review of two documents -- the primary Rezulin NDA and its Appendix -- which, if admissible, plaintiffs' counsel may present directly to the fact-finder while arguing his or her view as to their significance. Expert testimony interpreting Warner-Lambert's conduct in disclosing information to the FDA therefore [**34] will not assist the fact-finder in these cases.

58 *See Andrews, 882 F.2d at 708.*

59 Avorn Dep. 51-55, 142-46.

C. *Federal Rule of Evidence 403.*

Numerous portions of the opinions offered by these experts merely recite facts, or endorse opinions, expressed in the deposition of Dr. Misbin. Assuming that Dr. Misbin's testimony is ruled admissible at trial, the challenged opinions are excluded under *Rules 702and 403*, as cumulative and certain to waste time. [60] Plaintiffs' argument that references to Dr. Misbin's testimony serve merely as a "factual basis" for their experts' opinions ignores the fact that plaintiffs' experts also repeat Dr. Misbin's *opinions.* Accordingly, the proposed testimony about FDA procedures and regulations and disclosure of facts by Warner-Lambert to the FDA is inadmissible. [61]

60 The Court expresses no view on the admissibility of Dr. Misbin's testimony because the issue is not before the Court.

[**35]

61 As the challenged testimony is excluded on the foregoing grounds, the Court does not address the defendants' argument for exclusion under *Buckman.*

D. *Dr. Tolman's Testimony.*

Dr. Tolman's report largely to the effect that Warner-Lambert allegedly failed to provide the FDA with all necessary information regarding the risk of liver injury and that the FDA would not have approved Rezulin had it received different information. Defendants object to all of Dr. Tolman's proposed testimony on the ground that he arrived at these conclusions before having supporting data. [62]

62 To the extent that Dr. Tolman's testimony relates to disclosures to the FDA or speculation as to what FDA might have done in hypothetical circumstances, it is excluded for the reasons earlier cited with respect to similar testimony of other experts.

Dispositive here is Dr. Tolman's admission that he ". . . wrote a lot of the declaration [**36] without having the raw information in hand under the assumption that it would be provided to me, so it was sort of coming in around that time, but I wasn't able to reference it when I wrote the declaration . . ." [63] Courts applying the principles outlined in *Daubert* have held that an expert may not reach his conclusion first and do the research later. [64] Because Dr. Tolman wrote his report before

having the supporting data, his opinions are not "based upon sufficient facts or data" and do not proceed from "reliable principles and methods," as required by *Rule 702*. [65] Accordingly, all of Mr. Tolman's testimony is excluded.

63 Tolman Dep. 202-03.

64 *See Wills v. Amerada Hess Corp.*, No. 98 Civ. 7126, 2002 U.S. Dist. Lexis 1546 at *29 (S.D.N.Y. Jan. 31, 2002); *see also Claar v. Burlington N.R.R. Co., 29 F.3d 499, 502-03 (9th Cir. 1994)* ("Coming to a firm conclusion first and then doing research to support it is the antithesis of the [scientific] method.").

65 *FED. R. EV. 702(1)-(2).*

[**37] [*551] V. *History of Rezulin.*

Plaintiffs' expert Dr. Gale proposes to testify to a narrative reciting selected regulatory events concerning Rezulin, including Advisory Committee meetings, labeling changes, "Dear Doctor" letters, and approval and withdrawal decisions by regulators in the United States and abroad. [66] Warner-Lambert characterizes the proposed testimony as "nothing more than a repetition of the factual allegations in plaintiffs' complaint" combined with comments amounting to Dr. Gale's "spin" on the facts. [67] Preclusion is sought on the grounds that the testimony (1) is not "knowledge" because it relates to factual matter that does not implicate Dr. Gale's expertise or first-hand experience, (2) proceeds from a biased and unreliable methodology, and (3) would invade the province of the jury by presenting a narrative that advocates plaintiffs' version of the facts. Plaintiffs rejoin that Dr. Gale's narrative merely forms the basis for his opinions and helps to explain his reasoning to the jury, which entitles him to rely on facts of which he lacks personal knowledge.

66 *See* Gale Report PP55-72, 82-84. *See also* Gale Dep. 186-7.

[**38]

67 Plaintiffs essentially concede that there is nothing technical or scientific about Dr. Gale's narrative, which they say "is relevant to the testimony of most witnesses, both lay and expert, who will be testifying." Pl. Opp. 24.

Dr. Gale's "history of Rezulin" is merely a "narrative of the case which a juror is equally capable of constructing." [68] In Dr. Gale's own words, the purpose of this testimony is simply to "provide an historical commentary of what happened" [69] which, in his view, is "important to try and define the staging process" -- a term evidently meaning "background." [70] Such material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence. An expert is not required, for example, to comment that the transcript of the December 11, 1996 Advisory Committee "noted" in response to certain animal data, that "at least in rats we have reason to be concerned about what might happen ultimately in liver, a target tissue." [71] Likewise, the glosses that Dr. Gale interpolates into his narrative are simple inferences drawn from uncomplicated [**39] facts that serve only to buttress plaintiffs' theory of the case. As plaintiffs' Rezulin "historian," therefore, Dr. Gale "does no more than counsel for plaintiff will do in argument, *i.e.*, propound a particular interpretation of [defendant]'s conduct." [72] Accordingly, Dr. Gale's testimony relating to the "history of Rezulin" is inadmissible.

68 *Taylor*, 1997 U.S. Dist. LEXIS 3907, 1997 WL 154010, at *2.

69 Gale Dep. 187.

70 *Id.*

71 Gale Rep. P56.

72 *LinkCo, Inc.*, 2002 U.S. Dist. LEXIS 12975, 2002 WL 158551, at *2.; *accord GST, 192 F.R.D. at 111* ("the Court should not shift to [expert] witnesses the responsibility to give conclusory opinions and characterizations of the business conduct portrayed.")

VI. Foreign Regulatory Experience

Plaintiffs put forth Drs. Avorn, Bonkovsky, Day, Furberg, Gale, and Julie as expert witnesses regarding the actions of foreign regulators and Glaxo-Wellcome with respect to Rezulin. [73]

73 Dr. Avorn commented in his report that "evidence of Rezulin-induced liver damage was substantial enough for the company that marketed it in the United Kingdom, Glaxo-Wellcome, to make a decision to withdraw it from use in that country in November 1997 because of the rapid increase observed in instances of severe liver disease in patients taking the drug, and that company's concern that it might not be possible either to identify such at-risk patients in advance, or to reverse the progression of fulminant hepatic

necrosis once it had begun. Glaxo-Wellcome and Sankyo Pharma withdrew applications to market the drug in 28 countries in November and December 1997, including most of Europe. In October 1998 the Australian regulatory body, the Australian Drug Evaluation Committee, refused to approve Rezulin for use in that country because of concerns about its safety and whether it could possibly be monitored in a way that could prevent fatal hepatic events. A similar position was taken by the comparable review body in New Zealand two months later. The question was also reassessed by the UK Medicines Control Agency in 1998, and in March 1999 the MCA ruled that the available worldwide evidence indicated that the drug could not be used safely." Avorn Report 3. Dr. Avorn expressed the same opinions in his deposition. Avorn Dep. 158-63.

Dr. Bonkovsky opined that "early reports of hepatotoxicity in the United States and Japan led the United Kingdom's Medicines Control Agency to conclude the 'risk' of liver disease from troglitazone greatly outweighed any therapeutic 'benefit' from the drug. Introduced to the UK's marketplace in October of 1997, the drug was 'voluntarily' removed in December of 1997." Bonkovsky Report P8. His report states also that "it is interesting to note that on October 28, 1997 the United Kingdom Medicine's Control Agency proposed product warnings that Rezulin (troglitazone) 'is contraindicated in patients with severe hepatic impairment.'" *Id.* at P27.

Dr. Day discussed the decision of the United Kingdom's version of the FDA, the Medicines Control Agency (MCA) to remove troglitazone from the market. "Early reports of hepatotoxicity in the United States and Japan led the United Kingdom's version of the FDA, the Medicines Control Agency (MCA), to decide that the 'risk' of liver disease from troglitazone greatly outweighed any therapeutic 'benefit' from the drug. After being introduced to the UK's marketplace in October of 1997 the drug was 'voluntarily' removed from the marketplace in December of 1997, a mere 8 weeks or so after its introduction. Subsequent reports and analyses, in my opinion, confirm the validity of this decision to immediately remove troglitazone from te UK marketplace." Day Report P36.

Dr. Furberg commented that "the documented rates of liver toxicity led to disapproval of Rezulin by the regulatory agencies in many countries and withdrawal of Rezulin from the market in the UK in December of 1997." Furberg Report P30. Later, Dr. Furberg stated, "There was no reference made to ... the fact that regulatory agencies in other countries had withdrawn Rezulin from the market due to serious liver damage ..." *Id.* at P38(C). He said also that "the company's attitude and practice is in stark contrast to the emphasis on patient safety exemplified in Glaxo-Wellcome's deliberations in deciding to withdraw Rezulin from the United Kingdom market in December of 1997." *Id.* at P43. Dr. Furberg testified about these same foreign regulatory actions at his deposition. Furberg Dep. 196, 207-20.

Dr. Gale extensively discussed the history of Rezulin both in the United States and abroad. Gale Report PP55-72. He commented also about foreign regulatory experience stating: "It is extraordinary that, confronted with the identical safety concerns, Glaxo-Wellcome and its American counterparts should have drawn opposite conclusions concerning the advisability of keeping the drug on the market. It seems clear that Glaxo-Wellcome put the safety of patients before all other considerations, and that others involved did not." *Id.* at 83.

Defendants object also to the opinion at paragraph 56 in Dr. Gale's report, which they characterize as stating that Rezulin reached concentrations within rat livers 30 times greater than those in the plasma. In fact, that opinion consists merely of Dr. Gale quoting an FDA advisory committee panel that noted that "at least in rats we have reason to be concerned about what might happen ultimately in liver, a target tissue." *Id.* at P56. Dr. Gale's statement regarding animal studies was made in the context of his already-excluded "history of Rezulin" and therefore is inadmissible.

Dr. Julie opined that "to the extent that there were unknowns, the company should have provided that information to physicians much the same as Glaxo did when it withdrew troglitazone

from the UK in 1997." Julie Report P16. He testified as to the Australian experience with troglitazone at his deposition as well. Julie Dep. (11/22/02) 116-22.

[**40] [*552] Defendants seek to preclude all evidence, expert or otherwise, on the subject of foreign regulatory actions on the ground that it is irrelevant as a matter of law in a United States product liability litigation governed by United States law. They argue [*553] also that, even assuming that the evidence is relevant, it is only marginally so and that its potential for undue prejudice, confusion and waste of time warrants exclusion under *Rule 403*. With respect to some of the witnesses, including Dr. Avorn, defendants object also on the grounds of qualifications. Plaintiffs rejoin that the testimony is relevant to various issues. They do not address the *Rule 403* question.

A. *Relevance and Rule 403.*

The Court finds no legal basis upon which now to rule, as urged by Warner-Lambert, that testimony regarding foreign regulatory actions is irrelevant as a matter of law in a United States products liability case governed by American law. The authorities cited by the defendants do not stand for this broad proposition, but rather reflect decisions by various courts to exercise their discretion, in particular cases, to admit or exclude testimony on foreign standards or practices. Any ruling as to [**41] the relevancy of otherwise admissible evidence concerning foreign regulatory actions therefore would be premature.

B. Rule 702.

Assuming that evidence concerning foreign regulatory actions is relevant and admissible over *Rule 403* objections, plaintiffs' experts are not the appropriate vehicles for its introduction. The subject of the testimony is lay matter, similar in nature to Dr. Gale's "history of Rezulin." As review of the witnesses' reports and depositions makes clear, the challenged testimony focuses on a set of non-technical factual allegations -- specifically, the actions taken or not taken by foreign regulators or Glaxo-Wellcome with respect to Rezulin -- that plaintiffs would use as springboards for arguments about Warner-Lambert's conduct in the United States. [74] None of it qualifies as "scientific, technical or other specialized knowledge." [75] Accordingly, the proposed testimony of these witnesses is excluded under *Rule 702*.

74 The events to which the witnesses consistently refer are Glaxo Wellcome's alleged decision to withdraw Rezulin applications in several countries in late 1997, the alleged decisions of the Australian and New Zealand regulatory agencies not to approve Rezulin, and various alleged actions taken by the British Medicine Control Agency with respect to TGZ.

[**42]

75 Plaintiffs argue that Dr. Gale should be allowed to testify as a percipient witness because he was a member of the advisory panel that advised the British Medicines Control Agency ("MCA") on the risks and benefits of Rezulin and other TZDs, like Actos and Avandia in 1988, when Glaxo-Wellcome applied for the MCA's permission to reintroduce Rezulin on the British market. Dr. Gale's testimony, however, makes clear that his involvement was limited to submitting written material to the MCA, and his memory of the events, or even of the advice he gave, is tenuous. Gale Dep. 202-05. Moreover, allowing an expert like Dr. Gale to double as a percipient witness would raise a host of concerns under *Rules 702and 403. See United States v. Dukagjini, 326 F.3d 45, 53-56 (2d Cir. 2003)* (factual testimony of witness offered in dual role of case agent and expert likely to "attain[] unmerited credibility," bolster testimony of government fact-witnesses, and "stray from scope of ... expertise.")

VII. Warner-Lambert's Alleged Suppression of Research

One of the variations on the [**43] plaintiffs' theme that Warner-Lambert concealed information about the alleged toxicity of Rezulin is that the defendants allegedly suppressed the results of in-house scientific studies. Evidently, plaintiffs have designated Dr. Smith to deliver this argument at trial.

Dr. Smith's report concluded that "it is . . . apparent that Parke-Davis/Warner-Lambert management interfered dramatically [*554] with the scientific freedom of the above scientists." [76] He accused Warner-Lambert/Parke-Davis also of "suppressing scientific inquiry for the stated purpose of downplaying the hepatotoxic effects of TGZ in the published literature." [77]

76 Smith Report P41.

77 *Id.*

These opinions are based on Dr. Smith's review of "in-house documents, memos and emails" -- all material produced by the defendants in this case. [78] For example, he asserts that defendants in 1999 "attempted to block or slow down their own scientists" by "restricting their access to key databases on computers." [79] The sole bases for this assertion [**44] are statements of defendants' in-house scientists that are reproduced in an internal email that purports to discuss changes in employee access to computer servers. All of his proposed testimony relating to the charges of alleged "science-suppression" follows this format. Plaintiffs thus propose to use Dr. Smith to argue, based on other non-technical evidence, from the witness stand. The proposed testimony pertains to "lay matters which a jury is capable of understanding and deciding without the expert's help." [80] It is no more than "arguments and conclusory statements about questions of fact masquerading behind a veneer of technical language." [81]

78 *Id.* at PP41-45.

79 *Id.* P43.

80 *Andrews, 882 F.2d at 708.*

81 *LinkCo, Inc. v. Fujitsu Ltd.*, 2002 U.S. Dist. LEXIS 12975, 2002 WL 1585551, at *1.

It is for counsel to make the arguments about the significance of Warner-Lambert's conduct or omissions with respect to its researchers and not for an expert to testify as to [**45] whether the company did or did not do something. Furthermore, Dr. Smith's statements as to the intent or motives that underlay that same -- as yet undetermined -- conduct are improper "musings as to the defendants' motivations." [82] Finally, an expert who, like Dr. Smith, lacks personal knowledge may "only testify about the underlying facts if he [is] actually bringing to bear his scientific expertise." [83] Dr. Smith has no first-hand knowledge of the circumstances underlying his charge of data-suppression but brings no scientific or other technical expertise to bear on his testimony.

82 *See Taylor v. Evans,* 1997 U.S. Dist. LEXIS 3907, 1997 WL 154010, at *2. *See also generally* Section III *supra.*

83 *Pretter v. Metro N. Commuter R.R. Co.*, 2002 U.S. Dist. LEXIS 18332, No. 00 Civ. 4366, 2002 WL 31163876, (S.D.N.Y. Sept. 30, 2002), at *2.

Accordingly, all of Dr. Smith's testimony concerning Warner-Lambert's alleged interference with the independence of its in-house scientists or its alleged suppression of scientific [**46] research is inadmissible.

VIII. *Warner-Lambert's Alleged Failure Adequately to Protect Patients who Participated in the Rezulin Clinical Trials.*

Two of plaintiffs' proposed experts, Drs. Kronmal and Furberg, have rendered reports expressing the view that Warner-Lambert failed adequately to protect patients in clinical trials of Rezulin. [84] This testimony is not relevant under *Rules 401and 702* because no plaintiff in this MDL has been identified as a participant in a Rezulin clinical trial. The proposed testimony, even if otherwise admissible, therefore would not "assist the trier" to determine a fact in issue, as required by *Rule 702.* Accordingly, it is inadmissible. [85]

84 Kronmal Report PP12-22, 37(a); Furberg Report PP34, 42.

85 Dr. Furberg opined that Warner-Lambert's alleged disregard for the safety of participants in the clinical trials violated the guidelines of the International Conference on Harmonization, the Helsinki Declaration of 1964, and other clinical trial guidelines. Dr. Furberg's testimony is not relevant to this litigation for the reasons cited regarding Dr. Kronmal's testimony on the same subject. Accordingly, it too is inadmissible.

[**47] [*555] *IX. What Other Physicians Understood About Rezulin and its Benefits-Risks.*

Two of the plaintiffs' proposed experts, Drs. Gale and Bell, have rendered reports and/or testified in depositions regarding unidentified physicians' understandings of different occurrences, as well as their understanding of the risks and benefits of Rezulin.

Dr. Gale commented repeatedly in his deposition about physicians' understandings of various medications, stating that the significance of a new medication comparing favorably to a placebo "is not always understood" by physicians. [86] He opined also that physicians do not generally examine a package insert for safety information about a medication, stating that "the insert is -- in fact, many physicians, to be quite honest, don't see the inserts, because the insert is something that's only available to the patients, as the doctors do not open the package and take out the insert and read it." [87] He

later expressed the view that "now, a physician reading a statement saying 'reversible jaundice' thinks this is a harmless condition, self-limiting." [88]

86 Gale Dep. 154.

[**48]

87 *Id.* at 225.

88 *Id.* at 252.

Dr. Bell, too, testified about what other physicians understood about the risks and benefits of Rezulin. [89] He further expressed his view on what was known to the endocrinology community: "This tremendously high mortality rate associated with drug-induced liver disease was not well known and not well appreciated in the endocrinology community." [90]

89 Bell Report PP25-26. Dr. Bell stated, "The need to treat diabetes for the long term, the fact that the complications of diabetes occur only after years of inadequate control and the availability of other agents (with the ability to accomplish glycemic control of Hb Alc) influences the amount of acceptable risk that endocrinologists and others treating diabetes should accept when prescribing new therapies. I have analogized the problem on a simple 1 to 10 ranking scale. If disease and the immediate need for medicines fall on a spectrum from 1 to 10, an invariably fatal disease, like untreated lung cancer is a '10' and if a given drug cured this condition, a risk of death due to a serious adverse side effect would be very tolerable. On the other hand, if acne is a '1' and a given drug caused even one death or serious side effect, that is too much risk, that most people and physicians would not tolerate." *Id.* at P25.

Dr. Bell opined also that, "I would consider diabetes to be a '4', or if associated with heart disease, a '6'. Given that diabetes can be successfully treated with diet and exercise, the availability of several proven therapies to lower Hb Alc, and the fact that diabetes is a chronic condition whose effects are measured in years, if not decades, the need for a new medication which can lower Hb Alc but that comes with a side effect profile including death and acute fulminate liver failure is not acceptable. This is particularly true in the case of Rezulin where the onset of adverse event usually occurred in the first 4 to 12 months of therapy but the benefits of lower Hb Alc would not take effect until after several years of therapy." *Id.* at P26.

[**49]

90 Bell Report P47.

Dr. Bell devised also a 1-to-10 scale for risk that most physicians would tolerate when prescribing a new therapy, a scale that lacks sufficient scientific methodology to be considered expert testimony. Dr. Bell further stated that he had conferred with fifteen or so colleagues regarding that 1-to-10 scale, conceding that this was obviously not a "scientific methodological approach." Bell Dep. 245-47. Such conjecture, and a personal scale of risk assessment, do not rise to the level of "knowledge" required by *Rule 702*.

Defendants seek to preclude the above-cited testimony on the grounds that Drs. [*556] Gale and Bell are not qualified to opine as to what doctors in general think. Plaintiffs concede that opinions as to what "doctors in general think" would be inadmissible, but argue that the opinions challenged by the defendants do not fall into this category but rather pertain to the realm of permissible "completeness and accuracy" testimony. The parties' positions reflect a distinction drawn made by the *Diet Drugs* court. [91]

91 *In In re Diet Drugs,* 2000 U.S. Dist. LEXIS 9037, 2000 WL 876900 at *11-12 (E.D. Pa. June 20, 2000) (holding that the court "can easily preclude, from a *Daubert* viewpoint, the rendering of opinions by either of these witnesses as to . . . what doctors in general think, because the witnesses are not qualified for that," but that two particular experts were "fully qualified to opine on the medical facts and science regarding the risks and benefits of the [drugs] in question and to compare that knowledge with what was provided in the text of labeling and warnings on the [drugs] in question.")

[**50] The challenged opinions self-evidently discuss the practices of physicians as to reading labels or package inserts and their understandings of the contents of the Rezulin label. Accordingly, these opinions are excluded under *Rule 702* as speculative testimony. [92] Pursuant to the defendants' concession, and subject to relevance rulings to be made by the trial courts, these witnesses are not precluded from offering otherwise

admissible testimony as to the accuracy of the Rezulin label. [93]

92 *Id.* at *12.

93 Defendants allow, for instance, that Dr. Gale may testify about the medical definition of "reversible jaundice."

X. Decisions Made by Prescribing Physicians.

Plaintiffs propose to introduce analogous testimony through Dr. Furberg, to the effect that physicians would not have prescribed Rezulin if they had been provided with more complete information about Rezulin. "By misleading clinicians about the magnitude and seriousness of the liver problem, a large number of patients ended [**51] up taking Rezulin instead of safer, more effective and cheaper treatment alternatives. By withholding important safety information about Rezulin from providers, the Company also undermined the physician-patient relationship." [94]

94 Furberg Report P44.

Defendants seek to preclude this testimony on the grounds that (1) it is speculative because Dr. Furberg lacks expertise in treating diabetics or making risk-benefit assessments for drugs, [95] and (2) it improperly second-guesses the FDA's decisions as to the adequacy of the Rezulin label. Plaintiffs attempt to re-characterize Dr. Furberg's opinions as articulating general principles that physicians require accurate information on labels to make informed decisions and that prescriptions tend to decline when drug labels report adverse events in increasing numbers or frequency. Any physician, plaintiffs argue, is qualified so to opine, so it is irrelevant that Dr. Furberg lacks expertise in diabetology or risk-benefit assessment.

95 Dr. Furberg admitted that the treatment of diabetics and the evaluation of a drug's risk-benefit ratio is "not my field," Furberg Dep. 63, and admitted that he has no more than a "general sense" as to what drugs were available to treat Type II diabetes when Rezulin was approved. *Id.* at 62.

[**52] The clear import of Dr. Furberg's opinions is that physicians would not have prescribed Rezulin if Warner-Lambert had provided different information to physicians. Testimony similar to Dr. Furberg's was excluded as speculative in *Diet Drugs*. The court there excluded an expert opinion "as to whether [defendants's] failure to report certain information to the FDA led to more suffering and deaths of patients." [96] [*557] It held that the expert was "not qualified to opine on what decisions would have been made by the numerous physicians who prescribed diet drugs had they been provided with different labeling information. Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge." [97] Similarly speculative is Dr. Furberg's testimony as to whether physicians would have prescribed Rezulin if different information about Rezulin had been available. Accordingly, his testimony on this subject is inadmissible.

96 *In re Diet Drugs, 2001 U.S. Dist. LEXIS 1174, 2001 WL 454686, at *18.*

[**53]

97 *Id.*

XI. Duty to Warn Patients

Dr. Furberg's report included also statements regarding a company's duty to warn patients. Dr. Furberg first opined that "study subjects and regular patients also have the right to be fully informed by drug manufacturers about the drugs being tested or prescribed. To determine whether a treatment selection is acceptable, they need to be aware of all known favorable and unfavorable drug actions." [98] In paragraph 45(a) of his report he asserted that by allegedly withholding information Warner-Lambert violated "three basic patient rights issues." By violating these alleged "three basic patient rights," Warner-Lambert supposedly violated three corresponding "duties" of (1) full disclosure, (2) not harming others and (3) "distributional justice." [99]

98 Furberg Report P16 (emphasis in original).

99 The three basic "rights" allegedly are: (1) the right to "self-determination" (a notion akin to informed consent); (2) the right not to be harmed by others (derived from the so-called "principle of non-maleficence"); and (3) the right not to pay a certain price for a drug when an equally effective, but cheaper, one was available (ostensibly an aspect of the concept of "distributional justice"). Furberg Report P45.

[**54] Warner-Lambert asserts that Dr. Furberg is

offering personal opinions that run contrary to controlling law -- as embodied in FDA regulations and the learned intermediary doctrine -- insofar as they hold that pharmaceutical companies should provide accurate information to patients rather than physicians. Warner-Lambert argues also that Dr. Furberg's opinions invade the province of judge and jury insofar as they purport to articulate legal standards and then judge Warner-Lambert's conduct under those standards.

Plaintiffs resist the defendants' characterization of Dr. Furberg's opinions, asserting that they concern the "standard of conduct within the medical community" rather than the duties of the pharmaceutical companies to patients, and so do not invade the province of judge or jury. In the alternative, they contend that the opinions do not run contrary to controlling law because the learned intermediary doctrine [100] is inapplicable where, as here, Rezulin was marketed directly to consumers.

100 *See, e.g., In re Rezulin Prods. Liab. Litig., 133 F. Supp.2d 272, 281-82 (S.D.N.Y. 2001).*

[**55] Dr. Furberg's opinions concerning the rights of patients or the duties of pharmaceutical companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert. As the Second Circuit held in *United States v. Bilzerian,* expert testimony must be circumscribed carefully to ensure that "the expert does not usurp either the role of the trial judge in instructing the jury as to the applicable law and the role of the jury in applying that law to the facts before it." [101]

101 *926 F.2d 1285, 1294 (2d Cir. 1991).*

[*558] Plaintiffs counter that Dr. Furberg's proposed testimony does not invoke duties "required by law," but merely sets forth the "standards of conduct within the medical community." The argument is without merit. Dr. Furberg's opinions on the "three basic rights" of patients are at best thinly-disguised legal or quasi-legal principles. This is particularly evident in the case of the so-called "principle of self-determination," which is [**56] nothing but a formulation of the doctrine of informed consent. [102] Accordingly, Dr. Furberg's testimony on the "basic rights of patients" communicates a legal standard and so would encroach on the court's prerogative to instruct on the law. Dr. Furberg would fare no better if the Court were to view Dr. Furberg's opinions as articulating a "medical community standard" rather than a legal one: "testimony encompassing an ultimate legal conclusion based upon the facts of the case is not [admissible] *and may not be made so simply because it is presented in terms of industry practice."* [103]

102 According to Dr. Furberg the "right to self-determination requires that a patient be fully informed about potential benefits and risks so that he/she can make an informed decision regarding whether or not to take Rezulin. This was impossible since all relevant safety information was not made available by the Company and misleading and incomplete analysis of the data was given." Furberg Report P45(a).

In the circumstances, it is semantic sleight-of-hand for plaintiffs to contend that Dr. Furberg's opinion about "basic rights" is not a legal standard because the witness does not use the word "legal standards." (Pl. Opp. 42-43)

Another of Dr. Furberg's principles is a hybrid of the Hippocratic Oath and the Sixth Commandment: "the principle of non-maleficence signifies that no one should cause harm to others." *Id.* The Court would no more allow Dr. Furberg to testify here as to the "principle of non-maleficience" than it would permit a priest to testify about the Sixth Commandment under the guise of giving evidence of pharmaceutical industry standards.

[**57]

103 *United States v. Bilzerian, 926 F.2d 1285, 1295* (emphasis added).

Accordingly, testimony regarding patients' rights or a duty to warn patients is inadmissible.

XII. *Rezulin's Efficacy and its Risk-Benefit Ratio.*

Several of plaintiffs' experts propose to testify regarding Rezulin's efficacy, risk, and risk-benefit ratio. A precis of the challenged testimony and the Court's decision regarding each expert follow.

A. *Dr. Bell.*

Dr. Bell opined on the subject of drug-induced liver injury, stating: "I am also aware of evidence suggesting that a Rezulin reaction is worse in patients with pre-existing liver dysfunction." [104] He suggested also that

Rezulin may cause a variety of liver injuries other than those warned about in the label, including cirrhosis. [105] Defendants argue that Dr. Bell is not qualified to offer these opinions because he lacks pertinent expertise. [106] Plaintiffs do not dispute the point but instead deny that the challenged statements are opinions. Rather, they claim, the statements are "undisputed fact[s]" that [*559] form the basis for Dr. Bell's opinions. What [**58] opinions those might be, plaintiffs do not say.

104 Bell Report P50.

105 *Id.* at P33.

106 At his deposition Dr. Bell claimed "significant knowledge" about drug-induced liver injury but conceded that he is not an expert on the subject. Bell Dep. 20. He admitted also that he is not board certified in gastroenterology, the discipline that includes the subspecialty of hepatology, has never done a fellowship in hepatology, and never published a peer-reviewed article on drug-induced liver injury. *Id.* at 18-21.

This aspect of Dr. Bell's proposed testimony plainly consists of opinions -- opinions that are hotly contested and go to the heart of this litigation. In view of Dr. Bell's admitted lack of pertinent expertise, the testimony is excluded.

B. *Dr. Bonkovsky.*

Dr. Bonkovsky testified that he agreed with Dr. Gale's opinion that "there really was never evidence that there was that much more benefit to Rezulin compared with the already available on-the-market treatment." [107] Defendants [**59] object that Dr. Bonkovsky lacks the expertise to offer this opinion, citing his admission that he is "not an expert diabetologist or endocrinologist." [108] Plaintiffs rejoin that a physician's lack of expertise in the field on which he offers opinions affects its weight, not its admissibility.

107 Bonkovsky Dep. (9/27/01) 73.

108 *Id.* at 184.

As a broad proposition both sides are correct. The Second Circuit has taken a liberal view of the qualification requirements of *Rule 702*, at least to the extent that a lack of formal training does not necessarily disqualify an expert from testifying if he or she has equivalent relevant practical experience. [109] On the other hand, *Daubert* nevertheless requires district judges to determine whether the experience of a particular witness warrants placing that individual's view before the trier of fact.

109 *Mancuso v. Consolidated Edison of New York, 967 F. Supp. 1437 (S.D.N.Y. 1997)* (noting, on the basis of *McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1043 (2d Cir. 1995)*, that the Second Circuit "apparently follows" the Third Circuit's liberal interpretation of the *Rule 702* qualification requirement).

[**60] This Court finds Judge Conner's opinion in *Mancuso v. Consolidated Edison* [110] instructive. The court there precluded an internist, who worked primarily as a plaintiffs' expert in medical malpractice litigations, from testifying that PCB caused the plaintiff's injuries. The fact that the witness lacked formal training in toxicology or environmental medicine was not dispositive; rather, the Court found that his only relevant experience -- exposure, during his medical training, to "many patients [that] had environmental problems" -- was insufficient to establish the requisite specialized knowledge regarding the effects of PCBs on "living creatures." [111] Likewise, in light of Dr. Bonkovsky's lack of formal training in diabetology or endocrinology, the mere fact that some of his liver patients may have been exposed to Rezulin is insufficient to suggest that he has specialized knowledge on the risks and benefits of Rezulin -- a drug that, as a hepatologist, he presumably has had little occasion to prescribe.

110 *Id.*

111 *Id. at 1043.*

[**61] C. *Dr. Day.*

Dr. Day testified that he "strongly disagree[s] with Parke-Davis' delay in 'voluntarily' removing troglitazone from the US marketplace, which undoubtedly resulted in many needless cases of hepatotoxicity." [112] Defendants challenge Dr. Day's qualifications so to opine.

112 Day Report P36.

Dr. Day admitted that he is "not an expert on diabetes in the U.S." [113] He conceded also that a decision whether to keep Rezulin on the market would require an [*560] evaluation of the risks versus the benefits, a task for which he is not qualified. [114] Indeed plaintiffs concede that "because of Dr. Day's admitted lack of

familiarity with Rezulin's alleged benefits in treating diabetes, Plaintiffs will not offer testimony from him relating to what the Defendants call the *benefit* side of the risk/benefit analysis." [115] But plaintiffs cannot so limit the impact of Dr. Day's admissions. If he is unqualified to evaluate the benefit side of a risk-benefit analysis for Rezulin then, even assuming that he were [**62] qualified to comment on its risks in isolation (he is, after all, a hepatologist with experience in researching drug-induced liver disease), [116] he cannot testify about Rezulin's *relative* risk, as he would have to do in order to address the risk-befit ratio for Rezulin. Accordingly, Dr. Day's testimony regarding the efficacy or risk-benefit ratio for Rezulin is excluded.

113 Day (4/12/01) Dep. 14.
114 Day (11/26/02) Dep. 254.
115 Pl. Opp. 61 (emphasis added).
116 Day Report P8.

D. *Dr. Furberg.*

Dr. Furberg admitted that the efficacy data for Rezulin met FDA standards, under which a diabetes drug is considered effective if it lowers hemoglobin A1C, a measure of blood sugar. [117] But he proposes to testify that the FDA should "go beyond" this criterion to require that diabetes drugs should be shown to "reduce macrovascular complications." [118] He admits that this is his "public health viewpoint" and a personal "gold standard" that is not met by any diabetes drug currently [**63] on the market. [119] Defendants object to this testimony as unreliable speculation. Plaintiffs essentially concede the point, [120] but raise a host of insignificant objections which the Court rejects. Dr. Furberg's testimony regarding efficacy standards to which drug manufacturers ideally should adhere to "is not an 'expert' opinion, but rather a personal opinion about what standards [he] believes should apply to pharmaceutical company conduct." [121] It would not help the fact-finder to determine a fact at issue in this litigation. Accordingly, this testimony is excluded. [122]

117 Furberg Report PP21, 24; Furberg Dep. 64-65, 78-79.
118 Furberg Dep. 69, 73.
119 Specifically, Dr. Furberg said, "I take the position that the reason why we are treating patients is to reduce complications of the disease, and I like to see drugs - see whether the drugs reduce these complications. That is the gold standard and I like for these drugs that are to be used by millions of people for decades, I think we should have a standard where it requires all drugs [to] reduce these complications. That's my public health viewpoint and I've taken that position for many, many years and it applies broadly in medicine." Furberg Dep. 69. *See also* Furberg Report PP21, 46; Furberg Dep. 66, 73.

[**64]

120 Plaintiffs' only effort to oppose it undercuts their position. They assert that "defendants have misread [Furberg's] testimony," but their own paraphrase of the testimony confirms that Dr. Furberg proposes to testify about what the FDA should require of manufacturers. *See* Ptf. Opp. 41 ("In fact that testimony is that manufacturers of diabetes drugs should demonstrate that they actually reduce the complications they suffer.").
121 *See In re Diet Drugs, 2001 U.S. Dist. LEXIS 1174, 2001 WL 454586, at *18.*
122 The Court does not understand the defendants to be challenging here any testimony by Dr. Furberg to the effect that Rezulin clinical trials did or did not demonstrate efficacy as to particular conditions, *viz.* the prevention of heart attacks, strokes or amputations, which plaintiffs argue would be relevant to rebut the defendants' contention that Rezulin was proven efficacious in such regard. *See* Pl. Opp. 46. None of the testimony cited by the defendants on this particular motion *in limine* fits this description; rather, it embraces Dr. Furberg's view critique of Rezulin critical trials as measured against standards that he thinks the FDA ideally should adhere to.

[**65] E. *Dr. Julie.*

Dr. Julie proposes to testify regarding Rezulin's efficacy in treating diabetes [*561] and its risk-benefit ratio. [123] Warner-Lambert objects, arguing that Dr. Julie is unqualified because he is not an endocrinologist and lacks expertise in treating diabetes patients.

123 Julie Dep. (6/27/03) 102-13.

This does not in itself disqualify Dr. Julie. Defendants do not contest the general assertions in Dr. Julie's report that he is a board-certified gastroenterologist and has been a practicing physician in gastroenterology and hepatology for over fifteen years.

[124] They simply assert that "more specialized expertise" is required. Regrettably, however, the parties have not addressed the issue of Dr. Julie's qualifications with respect to the challenged testimony adequately. For example, plaintiffs have not brought to the Court's attention evidence in the record indicating that Dr. Julie has treated diabetic patients with Rezulin, rather than other therapies. Conversely, the defendants do not contest [**66] the plaintiffs' allegation that he has treated "numerous diabetic patients." [125]

124 Julie Report P1.

125 Pl. Opp. 53.

Accordingly, the defendants' motion *in limine* with respect to Dr. Julie's opinions on the efficacy and risk-benefit of Rezulin is denied without prejudice to renewal.

F. *Dr. Gale.*

Dr. Gale proposes to opine that the risk of Rezulin outweighed its benefits. As to the risk side of the equation he stated in his report that the chance of Rezulin-induced liver failure is 1 in 1000. That number derives from an unpublished December 19, 2000 report by Dr. David Graham, an FDA biostatistician. [126] Defendants seek to preclude all of Dr. Gale's testimony regarding the risks and benefits of Rezulin on the ground that his testimony about the risks would violate *Rules 702and 703.*

126 Gale Report P73.

[**67] 1. *Analysis under Rule 703.*

Under *Rule 703* a district court may allow an expert to testify based on inadmissible evidence, such as hearsay, if the evidence -- here the unpublished Graham report and its conclusion that the risk of Rezulin-induced liver failure is 1:1000--is "of a type reasonably relied upon by experts in the particular field." [127] Daubert's broad mandate requiring district courts to act as gatekeepers to prevent the admission of untrustworthy expert testimony applies fully to the analysis under *Rule 703*, and courts have broad discretion in determining whether hearsay evidence is "of a type reasonably relied upon by experts." [128] Moreover district courts must make an independent determination that the material in question is sufficiently reliable for experts in the field to rely upon it and are not bound merely "to accept expert testimony based on questionable data simply because other experts use such data in the field." [129] The Court, therefore, is not bound by Dr. Gale's assertion that, in his view, "anyone" would rely on Graham's report because it was a product of the FDA, an agency that (again, in his view) is widely regarded as the world's most rigorous [**68] and objective source of information on drugs generally and Rezulin in particular. [130] The parties have not brought to the Court's attention any authorities addressing the reliability of an [*562] expert's reliance on an unpublished study by an FDA employee. Thus the analysis proceeds in the framework of established principles under *Rules 702and 703.*

127 *FED. R. EV. 703.*

128 *See United States v. Locascio, 6 F.3d 924, 938 (2d Cir. 1993).*

129 *Id.; accord MTX Communications Corp. v. LDDS/Worldcom, Inc., 132 F. Supp.2d 289 (S.D.N.Y. 2001).*

130 "This report was produced by the FDA, which is widely regarded as the permiere drug-regulating authority in the world. It would be considered by a general observer such as myself as a completely impartial report. In common with the rest of the world, I regard the FDA as being objective and scientific in its statements and evaluations, and therefore I don't know of anywhere better to go for information . . . [the] report . . . was produced by an agency which now had there or four years of experience with Rezulin, where there were many other people who were fully aware of the data and able to comment on it, so, for this reason, I think it should be considered the best available information." Gale Dep. 249.

[**69] **First,** defendants correctly note that Dr. Gale viewed the unpublished Graham report as "final" and "definitive." [131] And while Dr. Graham labeled the study as a "Final Report," the same study later was published with the conclusion that the incidence of acute liver failure was 1:4200 -- less than one-fourth the rate in the earlier, unpublished report. [132] Moreover, plaintiffs do not dispute that under the FDA's own regulations the unpublished report did not qualify as an official position of the FDA, a fact of which Dr. Gale apparently was unaware. [133] Thus the December 2000 Graham report itself would appear to be untrustworthy when relied upon, as did Dr. Gale, as a definitive opinion of the FDA. [134]

Moreover, Dr. Gale admitted that he made no effort to ascertain whether the unpublished study was, in fact, "definitive" or merely a preliminary draft. [135] More importantly, however, the Court harbors concerns as to why Dr. Gale would, in a report prepared for this litigation, rely on the 1:1000 ratio expressed in an unpublished study authored by another person, while eschewing his own published, peer-reviewed view that the ratio was in the far lower range of 1:8000 to 1: [**70] 20,000. [136] This omission is left unexplained and suggests that Dr. Gale's reliance on the unpublished Graham report was not based on scientific method but on the expediencies of this particular litigation. [137] Taken together, all [*563] of these factors lead the Court to conclude that Dr. Gale's reliance on the unpublished Graham report does not comport with *Rule 703*. To the extent that Dr. Gale's opinions regarding the risk of Rezulin are based on the 1:1000 ratio found in the unpublished Graham report they therefore are inadmissible. [138]

131 Gale Report P73 ("With respect to liver damage, I have considered as definitive the final report of the FDA") (citing the Graham December 19, 2000 study); *see also* Gale Dep. 246.

132 P. Ex. 16, Graham, *et al.*, "Incidence of Idiopathic Acute Liver Failure and Hospitalized Liver Injury in Patients Treated with Troglitazones," *American Journal of Gastroenterology,* 98:1, 175-179 (2003).

133 "A statement or advice given by an FDA employee orally, or given in writing but not under this section or *§ 10.90*, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, *does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed." 21 C.F.R. § 10.85(b) (West 2003).*

[**71]

134 Graham, *et al.*, "Incidence of Idiopathic Acute Liver Failure and Hospitalized Liver Injury in Patients Treated with Troglitazones," *American Journal of Gastroenterology,* 2003, 98:1, 175-179.

Plaintiffs' claim that the "reasonable reliance" requirement of *Rule 703* is met because the unpublished Graham report was eventually published and concluded that "troglitazone is a potent hepatotoxin, conferring a substantially increased risk of acute liver injury including [Acute Liver Failure]," is disingenuous in light of the fact that the conclusion reached in that publication diverged substantially from the previous unpublished draft.

135 *See* Gale Dep. 249.

136 Gale, E. "Lessons from the Glitazones: A Story of Drug Development," *The Lancet* 357:1870-75, at 1871.

137 Plaintiffs' "argument" that under *Daubert* an opinion may be reliable even if not based on epidemiological data is irrelevant in this context where the issue is Dr. Gale's failure to consider indisputably relevant and available data.

138 Plaintiffs argue that Dr. Gale's opinion on the risks of Rezulin is not based solely on the Graham report, but on several other sources, including Gale's pre-litigation peer-reviewed study in the *Lancet,* his review of liver damage in Rezulin clinical trials, the circumstances of Glaxo-Wellcome's decision to withdraw TGZ in Britain. *See* Gale Dep. 202-205. This argument appears to be unpersuasive at least with respect to Dr. Gale's ability to opine as to the *incidence* of liver injury in Rezulin users, as by his own admission, the only source for his ratio is the unpublished Graham report. Even Dr. Gale's own report in this case does nto rely on his *Lancet* article as a source for his incidence opinion.

[**72] 2. *Analysis under Rule 702.*

Additional aspects of Dr. Gale's proposed testimony lead to the conclusion that his opinions on the ratio of Rezulin-induced liver failure are unreliable also under *Rule 702* and *Daubert.*

First, there is Dr. Gale's admission that he adopted Graham's 1:1000 ratio without considering two epidemiological studies (one published, the other available to him through plaintiffs' counsel) that addressed this very subject but reached drastically different conclusions -- *viz.* a ratio of 1:10,000, which is less than one-fourth that in the Dr. Graham piece. [139] This omission is especially glaring against Dr. Gale's own deposition testimony that in looking at the level of risk of acute liver failure from Rezulin "all evidence should be taken into account," [140] including epidemiological

studies. [141] Although the Selby-Chan study had not been published at the time of Dr. Gale's deposition plaintiffs do not dispute that an abstract and draft were given to plaintiffs' counsel before Dr. Gale's deposition, and that Dr. Selby had been deposed in this case before Dr. Gale. Yet Dr. Gale testified he never had reviewed the abstract or the study and was unaware [**73] that Dr. Selby had been deposed this case. [142] Dr. Gale's selectivity in defining the universe of relevant evidence thus violated his own standard of proper methodology that "all evidence should be taken into account," which suggests that he does not apply the same rigor in the courtroom that he would apply to his medical endeavors. [143] As the court held in *Lust v. Merrell Dow Pharm., Inc.,* [144] an expert may not "'pick and chose' from the scientific landscape and present the Court with what he believes the final picture looks like." [145] Similarly, in a case cited by the plaintiffs, this Court precluded an expert from testifying in part because he ignored available information that was vital to his opinion. [146]

139 *See* Gale Dep. 273-74.

140 *Id.* at 279-80. *See* Faich and Mosley, "Troglitazone (Rezulin) and Hepatic Injury," *Journal of Pharmacoepidemiology* (December 2001) (available more than six months before the date of Dr. Gale's report; concluded that risk of acute liver failure from Rezulin at most 1:10,000 and decreased with each year that Rezulin available.); Selby and Chan, "A Cohort of Incidence of Acute Hepatic Failure and Lesser Degrees of Liver Injury in Patients with Diabetes Mellitus," *Hepatology* (October 2001) (quantified the risk of acute liver failure at rate of 1:10,000).

[**74]

141 *Id.* at 110.

142 Gale Dep. 273.

143 *Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152, 143 L. Ed. 2d 238, 119 S. Ct. 1167.*

144 *89 F.3d 594 (9th Cir. 1996).*

145 *Id. at 596.*

146 *MTX Communic. Corp. v. LDDS/WorldCom, Inc., 132 F. Supp.2d 289, 292-93 (S.D.N.Y. 2001).*

While as a general proposition plaintiffs are correct that neither *rule 702* nor *Daubert* requires experts to rely on epidemiological data, the dispositive fact here is that Dr. Gale pointedly ignored directly relevant scientific data in violation of his own standards.

[*564] **Second,** when confronted with the 1:10,000 incidence rates described in the two epidemiological studies that he did not review, Dr. Gale shifted his position, claiming for the first time the "acceptable risk [for Rezulin] is zero" [147] because Rezulin offers "no true benefit." In a similar vein, he testified that he "challenged the whole concept of what is an acceptable level of risk" for Rezulin because "whether it's one in 1,000 or one in 10,000 or even one in 20,000, I will not use that [**75] drug, because there is no drug worth dying for when it comes to the treatment of diabetes." [148]

147 Gale Dep. 369.

148 *Id.* at 312.

The basis for this view, Dr. Gale testified, is that "[Rezulin] is special." [149] But Dr. Gale acknowledged that death is a side effect of other medications on the market [150] and that diabetes medications that he prescribes, such as insulin, metformin and sulfonylureas, also carry serious risks, albeit ones that (to his mind) are not comparable to Rezulin because the benefits of those other drugs, on balance, are higher than those of Rezulin. Moreover, as this Court has written, many of plaintiffs' other experts have acknowledged that "Rezulin was enormously beneficial to many patients." [151] Dr. Gale's view that there is no acceptable risk for Rezulin therefore is so extreme that it appears to be shared by no other expert inside or outside this litigation.

149 *Id.* at 270.

[**76]

150 *Id.* at 279.

151 *In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 68 (S.D.N.Y. 2002).*

To be sure, *Daubert* explicitly dispensed with the *Frye* general-acceptance standard and held that "some propositions . . . are too particular, too new, or of too limited interest to be published." [152] But none of these factors applies to the subject of the incidence rate of Rezulin-induced liver failure, as is evident on this very record which includes relevant publications, including Dr. Gale's. In the circumstances, the assertion that Rezulin is "special" suggests to the Court that Dr. Gale is not employing in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field, or at the very least this particular expert. [153]

152 *509 U.S. at 593.*

153 *Kumho Tire, 526 U.S. at 152, 143 L. Ed. 2d 238, 119 S. Ct. 1167.*

Plaintiffs' attempt to deny that the "no acceptable risk" opinion conflicts with Dr. Gale's report -- where he consistently opined that the risk-benefit of Rezulin was unacceptable because the risk, expressed in terms of incidence, was 1:1000 -- is baseless. Dr. Gale did not hint anywhere in his report that Rezulin was so ineffective that no level of risk would be acceptable.

[**77] 3. *Liver Enzyme Testimony.*

Defendants object also to Dr. Gale's proposed testimony concerning changes in liver enzymes. Relying on an article by Aithal and Day entitled "The Natural History of Histologically Proved Drug Induced Liver Disease," Dr. Gale opined that the "reversibility of changes in liver enzymes does not necessarily imply that the episode is either concluded or benign" and that "liver inflammation can and often does persist after the drug has been withdrawn." [154]

154 Gale Report P74; Gale Dep. 151-52, 232-33.

[*565] Defendants argue that this testimony is unreliable because the article Dr. Gale relies upon does not mention Rezulin, Dr. Gale is not aware of any study or article that reaches a conclusion similar to Aithal-Day, and he has not seen any peer-reviewed literature consistent with his opinion. [155] Second, defendants argue that Dr. Gale is unqualified to give this testimony because he is a doctor specializing in the treatment of diabetic patients, but not a hepatologist, and that he [**78] has not demonstrated sufficient experience dealing with drug-induced liver injury, to testify about liver enzyme changes. Plaintiffs do not oppose, and thus are deemed to admit, the defendants' contentions regarding the unreliability of the challenged testimony. As to Dr. Gale's qualifications, plaintiffs merely assert that defendants' position "carries expert qualification to an illogical extreme" and cite cases outside this Circuit for the general proposition that lack of specialization merely affects the weight, not the admissibility, of expert testimony.

155 *See* Gale Dep. 258-59.

The Court finds that Dr. Gale's opinions on the elevation of liver enzymes is unreliable for the reasons stated by the defendants. Accordingly, his testimony on the subject is inadmissible.

XIII. *Dr. Julie's Opinions on Dr. Watkins's Spreadsheets.*

Dr. Julie opined that Rezulin can cause cirrhosis, basing this view in part on certain spreadsheets created by Dr. Watkins, a hepatology consultant to Warner-Lambert. [**79] [156] Defendants challenge this testimony on the ground that it is not "based upon sufficient facts or data" because it is contrary to undisputed evidence in the record -- more specifically, Dr. Watkins's own testimony as to the meaning of the spreadsheets. Plaintiffs argue that Dr. Julie's proposed opinions are consistent with deposition testimony that Dr. Watkins's gave regarding a different set of spreadsheets in a separate Rezulin case.

156 Julie Report 3, 8, 11, 17.

The spreadsheets in question here were prepared by Dr. Watkins to track adverse events associated with Rezulin. In various columns he listed information including the names of the patients, their ages, and the dates of Rezulin use. In a column headed "Comments," Dr. Watkins noted information about existing medical conditions or adverse events reported for a particular patient. In some instances he noted the term "cirrhosis." In another column (or columns), he noted whether Rezulin, in his view, was "possibly" or "probably" the cause of the [**80] adverse event -- there appear to have been 33 cases with the notation "cirrhosis" of which two were classified as "probably" and nine were classified as "possibly." [157]

157 The exhibit submitted to the Court is nearly illegible so it is impossible to determine which column or columns the "probable" and "possible" notations are found in. In any event, there is no dispute between the parties that the document does include such notations.

At his deposition Dr. Watkins testified as to what he meant when he included the term "cirrhosis" in the "Comments" column -- he meant only that "cirrhosis was either reported or some evidence of cirrhosis was present. It was not in any way a statement that Rezulin had caused the cirrhosis." [158] He testified further that it would be inaccurate to construe his spreadsheets as proof that

Rezulin caused cirrhosis. [159] He stated also that the spreadsheets that Dr. Julie relied on were designed as a basis for causation assessments [*566] with respect to acute, rather than chronic, [**81] liver injuries such as cirrhosis. [160] Consequently, he stated, "the fact that cirrhosis appears in my comments section is not related to my assessment . . . [it is merely noted] as a feature of the case." [161]

158 Watkins (8/1/02) Dep. 535-36.
159 *Id.* at 535-57.
160 Watkins (8/1/02) Dep. 512-4.
161 *Id.* at 536-7.

Plaintiffs claim that Dr. Watkins' definition of "probable" with respect to a different set of spreadsheets, not at issue here, is consistent with Dr. Julie's testimony about the subject spreadsheets. In that context, Dr. Watkins said that the term "probable" meant that "[Rezulin] contributed significantly to the liver event" or that he believed "with a reasonable degree of certainty [that the adverse event was] at least in part related to Troglitazone." [162]

162 Watkins (4/26/02) Dep. 46-47, attached as Exhibit 22 to plaintiffs' Appendix.

[**82] It may well be that there is an issue of fact as to what Dr. Watkins intended when he used the word "cirrhosis" in the spreadsheets relied upon by Dr. Julie. By no stretch of the imagination, however, could one say that Dr. Julie's assumption as to what Dr. Watkins meant be regarded as an appropriate basis upon which to ground expert testimony. He proposes to give an expert opinion based on a guess, not facts.

XIV. *Conclusion.*

For the foregoing reasons, the defendants' motion *in limine* is granted to the extent set forth above and otherwise denied.

SO ORDERED.

Dated: March 15, 2004

Lewis A. Kaplan

United States District Judge

*** Slip Sheet ***

Document

LEXSEE 750 A.2D 518

J. S. ALBERICI CONSTRUCTION COMPANY, INC., Defendant Below, Appellant, v. MID-WEST CONVEYOR COMPANY, INC., a/k/a MID-WEST CONVEYOR INTERNATIONAL a/k/a DEARBORN MID-WEST CONVEYOR CO., and CHRYSLER CORPORATION, Defendants Below, Appellees.

No. 216, 1999

SUPREME COURT OF DELAWARE

750 A.2d 518*; *2000 Del. LEXIS 46

January 19, 2000, Submitted
February 7, 2000, Decided

SUBSEQUENT HISTORY: [**1] Released for Publication February 23, 2000.

PRIOR HISTORY: Court Below: Superior Court of the State of Delaware in and for New Castle County. C.A. No. 96C-07-90.

DISPOSITION: REVERSED and REMANDED.

COUNSEL: William I. Cattie, III, Esquire (argued) and Barbara A. Fruehauf, Esquire, Cattie and Fruehauf, Wilmington, Delaware, for Appellant.

Paul M. Lukoff, Esquire and Sheldon K. Rennie, Esquire (argued), Prickett, Jones, Elliott & Kristol, Wilmington, Delaware, for Appellees.

JUDGES: Before WALSH, HOLLAND, and HARTNETT, Justices.

OPINION BY: WALSH

OPINION

[*518] Appeal from Superior Court.

WALSH, Justice:

This is an interlocutory appeal from a Superior Court ruling in a personal injury [*519] action. The court held, *inter alia,* that a subcontractor/defendant has a duty to defend a contractor/co-defendant under an indemnification agreement for the contractor's own negligence. In so holding, the Superior Court rejected the subcontractor's contention that the agreement should be interpreted under Delaware rather than Kansas law.

We conclude that the Superior Court's decision to interpret the indemnification agreement under Kansas law [**2] was in error because that State's law permitting contractual indemnification for one's own negligence is clearly repugnant to the legislatively-defined public policy of Delaware. Accordingly, we reverse and remand this action for further proceedings.

I

The Superior Court's ruling was made in the context of cross-motions for summary judgment in which the following facts were undisputed. The Chrysler Corporation ("Chrysler"), a Delaware corporation with its corporate headquarters in Michigan, began a refurbishing project at its assembly plant in Newark, Delaware in April 1994. In furtherance of this project, Chrysler hired Midwest Conveyor International, Inc., ("Midwest"), a Delaware corporation with its corporate headquarters in Kansas, as the general contractor. Midwest, in turn, hired several subcontractors, including J. S. Alberici Construction Company ("Alberici"), a company headquartered and incorporated in Missouri, to perform demolition and rehabilitation work at the plant.

All of the subcontracting companies were required to sign a subcontractual agreement containing the following indemnification provision:

The SUBCONTRACTOR shall

> indemnify, hold harmless and defend [**3] MID-WEST and the OWNER, their respective employees, agents, servants, and representatives from and against any and all losses, damages, expenses, claims, suits and demands of whatever nature resulting from damages or injuries, including death, to any property or persons, caused by or arising out of any action, omission or operation under this Subcontract or in connection with the work attributable to the SUBCONTRACTOR, any of its subcontractors, any of its materialmen, any of their respective employees, agents, servants, and representatives, or any other person, including MID-WEST and the OWNER, their employees, agents, servants, and representatives, provided, however, that the SUBCONTRACTOR shall not be required to indemnify MIDWEST or the OWNER or their respective employees, agents, servants, and representatives hereunder for any damages or injuries, including death, to any property or persons caused solely and exclusively by the negligence of either MID-WEST or the OWNER or their respective employees, agents, servants and representatives.

The agreement also recited that it would be construed under the laws of the State of Kansas.

On July 10, 1994, Ronald Al-Uqdah, a worker [**4] involved in the refurbishment project, [1] was injured after falling through a metal plate which had not been securely fastened. Alberici was responsible for maintenance in the area where Al-Uqdah was injured. On July 10, 1996, Al-Uqdah and his wife filed a personal injury action in Superior Court naming Chrysler, Midwest, and Alberici as defendants.

> 1 Al-Uqdah was an employee of Commercial Contracting Corporation which, although operating as a subcontractor, had a direct contract with Chrysler.

On October 25, 1996, Midwest filed a cross-claim against Alberici for contribution and/or indemnification pursuant to the subcontract agreement. Soon after, both Midwest and Alberici filed cross-motions for summary judgment. In its motion, Alberici argued that the indemnification provision was contrary to the public policy [*520] of Delaware law as expressed in *6 Del. C. § 2704(a)* and, therefore, notwithstanding the language of the contract, Kansas law should not apply.

On April 20, 1999, the Superior Court issued [**5] an Opinion and Order denying both parties' motions for summary judgment based on its determination that the record reflects the existence of genuine issues of material facts concerning negligence and causation. The court ruled, however, that the indemnification provision is controlled by Kansas law and is enforceable. Thus, the court held that Alberici has a duty to defend Midwest and Chrysler under the terms of the subcontract agreement. We granted review of that interlocutory ruling.

II [2]

Delaware courts will generally honor a contractually-designated choice of law provision so long as the jurisdiction selected bears some material relationship to the transaction. *Annan v. Wilmington Trust Co., Del. Supr., 559 A.2d 1289, 1293 (1989).* Although the law of a foreign jurisdiction cannot be used to interpret a contract provision in a manner repugnant to the public policy of Delaware, *Travelers Indem. Co. v. Lake, Del. Supr., 594 A.2d 38, 45 (1991)*, there is corollary policy in favor of recognizing and enforcing rights and duties validly created by a foreign law. *Skillman v. Conner, Del. Super., 38 Del. 402, 193 A. 563, 566 (1937).* A [**6] mere difference between the laws of two states will not necessarily render the enforcement of a cause of action arising in one state contrary to the public policy of another. *Id.*

> 2 The Superior Court's holding implicates an issue of law and is subject to *de novo* review. *Colonial Educ. Assoc. v. Board of Educ. of Colonial Sch. Dist., Del. Supr., 685 A.2d 361, 363-64 (1996).*

Alberici does not dispute that the indemnification provision would be enforceable under Kansas law. Alberici does contend, however, that the indemnification provision, to the extent it permits a party to contract away liability for its own negligence, is clearly repugnant to the public policy of Delaware as set forth in *6 Del. C. § 2704(a)* and, therefore, unenforceable. *Section 2704(a)*

states in relevant part:

> A covenant, promise, agreement or understanding in, or in connection with or collateral to, a contract or agreement relative to the construction, alteration, repair or maintenance of a road, [**7] highway, driveway, street, bridge or entrance or walkway of any type constructed thereon, and building, structure, appurtenance or appliance, including without limiting the generality of the foregoing, the moving, demolition and excavating connected therewith, purporting to indemnify or hold harmless the promisee or indemnitee or others, or their agents, servants and employees, for damages arising from liability for bodily injury or death to persons or damage to property caused partially or solely by, or resulting partially or solely from, or arising partially or solely out of the negligence of such promisee or indemnitee or others than the promisor or indemnitor, or its subcontractors, agents, servants or employees, *is against public policy and is void and unenforceable,* even where such covenant, promise, agreement or understanding is crystal clear and unambiguous in obligating the promisor or indemnitor to indemnify or hold harmless the promisee or indemnitee from liability resulting from such promisee's or indemnitee's own negligence.
>
> (emphasis supplied)

Midwest responds that simply because there is a difference between Delaware and Kansas law with regard to the permissible [**8] scope of indemnification in the present context, does not mean there is a *per se* fundamental public policy at stake sufficient to prompt a Delaware court to refuse to enforce a contract valid under Kansas law. Rather, Midwest notes, the foreign [*521] law must be clearly repugnant to the public policy of Delaware or no state would ever apply a foreign state's law that was different from its own. Midwest argues that a foreign law is repugnant to the public policy of Delaware only if it violates some fundamental principle of justice, prevalent conception of morality or deep-rooted tradition of society. *See Loucks v. Standard Oil Co., N.Y. Ct. App., 224 N.Y. 99, 120 N.E. 198, 202 (1918)*; *16 Am. Jur. 2d Conflicts of Laws § 25* (1998). The Kansas law that would otherwise enforce the indemnification provision, the argument runs, cannot be so described.

This case poses significant competing arguments in a choice of laws setting. On the one hand, there is the strong policy in favor of enforcing another state's laws. Conversely, *section 2704(a)* contains an explicit statement of public policy by the Delaware General Assembly that is difficult to ignore. Midwest argues that [**9] because the purpose motivating the legislature's statement of public policy is not specified, nor the evil sought to be remedied identified, this Court should not permit the contractually-selected law of another jurisdiction to be cast aside. We are of the view, however, that courts faced with a clear legislative statement of public policy should not attempt to parse that policy or speculate concerning the degree of egregious conduct sought to be prevented.

Although *section 2704(a)* does not indicate the specific purpose underlying the policy expressed, it does express in broad terms the "promisee," "indemnitee" and "others" as a class prohibited from contracting away liability for their own negligence. The present language of the statute is apparently a direct response to an earlier Superior Court decision which narrowly construed the statutory purpose. In *Wenke v. Amoco Chems. Corp., Del. Super., 290 A.2d 670, 673*, the Superior Court construed the purpose of *section 2704(a)* to be as follows:

> The purpose of the statute is to prevent owners and their affiliated preconstruction professional people who furnish plans, designs and specifications from contracting [**10] away their duty to stand behind their product. There is no clear or specific reference in the statute to contractors or subcontractors engaged in the actual construction of buildings or to the services which they may render in repairing or renovating the same.

In 1988, however, *section 2704(a)* was broadened through an amendment by the Delaware General Assembly to include anyone in a subcontractor/contractor

relationship in the construction context. 66 Del. Laws, c. 394, §§ 1-5. That is this case.

Section 2704(a) is clear on its face: a contractual provision requiring one party to indemnify another party for the second party's own negligence, whether sole or partial, "is against public policy and is void and unenforceable." Courts are not free to disregard that declaration of policy. Accordingly, we find this statutory language compels the conclusion that enforcing Kansas law on this issue would be clearly repugnant to the public policy of Delaware.

III

For the foregoing reasons, we reverse the decision of the Superior Court and remand this action for further proceedings.

*** Slip Sheet ***

Document

LEXSEE 88 N.Y.2D 413

Lama Holding Company et al., Appellants, v. Smith Barney Inc. et al., Respondents.

No. 144

COURT OF APPEALS OF NEW YORK

88 N.Y.2d 413; 668 N.E.2d 1370; 646 N.Y.S.2d 76; 1996 N.Y. LEXIS 1187

May 1, 1996, Argued
June 13, 1996, Decided

PRIOR HISTORY: Appeal, by permission of the Court of Appeals, from an order of the Appellate Division of the Supreme Court in the First Judicial Department, entered May 25, 1995, which modified, on the law, and, as modified, affirmed an order of the Supreme Court (Alice Schlesinger, J.), entered in New York County, granting, in part, a motion by defendants to dismiss the complaint. The modification consisted of granting the motion to dismiss the complaint in its entirety.

Lama Holding Co. v Smith Barney, 215 AD2d 314, affirmed.

DISPOSITION: Order affirmed, with costs.

HEADNOTES

Fraud -- Fraud in Inducement -- Corporate Merger -- Tax Liability of Shareholder Consenting to Merger

1. In an action by plaintiffs, two parent corporations and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner which, due to a change in the tax laws that plaintiffs were unaware of, resulted in tax liability of over $ 33 million to plaintiffs, damages consisting of the amount of taxes plaintiffs were required to pay do not support causes of action for fraud and misrepresentation which allegedly induced plaintiffs' vote for the merger. Plaintiffs' tax liability was not caused by an act or omission by defendants, but rather by the repeal of the General Utilities Doctrine under the Tax Reform Act of 1986, six months prior to the meeting at which the fraudulent inducement allegedly occurred. Plaintiffs' participation in the merger was a taxable event which required the payment of taxes as a result of the repeal of the General Utilities Doctrine. The complaint does not allege how defendants' failure to disclose the identity of the merger partner or that several directors would be treated favorably by the merger partner for their votes, was fraudulent, or proximately caused the tax consequences to plaintiffs of participating in the merger. Plaintiffs additionally fail to allege how defendants could possibly have known of plaintiffs' ignorance of the change in the tax laws, requiring defendants, as opposed to plaintiffs' own financial and legal counsel, to provide such information.

Fraud -- Fraud in Inducement -- Corporate Merger -- Necessity of Loss Suffered by Plaintiff

2. In an action by plaintiffs, two parent corporations and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner which, due to a change in the tax laws that plaintiffs were unaware of, resulted in tax liability of over $ 33 million to plaintiffs, plaintiffs' claims of fraud based upon alleged misrepresentations by defendant that induced plaintiffs to vote for the merger, even if sufficiently alleged, were correctly dismissed. Plaintiffs would be limited to recovering their losses, and there were no losses because plaintiffs received more than twice the fair market value for their shares.

Fraud -- Fraud in Inducement -- Corporate Merger -- Loss of Shareholder's Opportunity for Direct Sale of Stock

3. In an action by plaintiffs, two parent corporations

and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner which, due to a change in the tax laws that plaintiffs were unaware of, resulted in tax liability of over $ 33 million to plaintiffs, the loss of an alternative contractual bargain involving the merger partner's direct purchase of the holding company from its parents which would potentially eliminate the holding company's tax liability, cannot serve as a basis for fraud or misrepresentation damages because the loss of the bargain was undeterminable and speculative. Nowhere do plaintiffs allege that the merger partner's refusal to go forward with the proposed alternative purchase was because of defendant's fraud rather than an independent business decision made by the merger partner.

Fraud -- Fraud in Inducement -- Out-of-Pocket Rule -- Tax Liability Resulting from Corporate Merger

4. In an action by plaintiffs, two parent corporations and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner which, due to a change in the tax laws that plaintiffs were unaware of, resulted in tax liability of over $ 33 million to plaintiffs, plaintiffs' claim for recovery of the payment of taxes, couched as consequential damages or otherwise, based upon defendant having fraudulently induced plaintiffs to vote for the merger, is barred by the out-of-pocket rule applicable to fraud actions. The recovery of consequential damages naturally flowing from a fraud is limited to that which is necessary to restore a party to the position occupied before commission of the fraud. Plaintiffs' tax payment does not naturally flow from defendant's alleged fraud, but from a change in the tax laws, and recoupment by plaintiffs of the taxes paid would put it in a better position than if they retained their shares.

Corporations -- Merger -- Breach of Fiduciary Duty of Disclosure -- Delaware Law

5. In an action by plaintiffs, two parent corporations and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner, plaintiffs have failed to sufficiently plead a cause of action for breach of fiduciary duty under Delaware law based upon allegations that defendant's misrepresentation of material facts concerning the merger partner and the concomitant tax consequences to plaintiffs of voting in favor of the merger, breached defendant's fiduciary duty of disclosure. Plaintiffs do not allege how their receipt of the undisclosed information prior to the meeting at which they consented to the merger would have affected plaintiffs' tax consequences under the merger. At any rate, the undisclosed information was provided to all of defendant's shareholders, including plaintiffs, in the proxy material. Plaintiffs had all of the previously undisclosed material prior to casting their vote in favor of the merger. Therefore, plaintiffs' decision to vote in favor of the merger and take its approximately $ 90 million profit was an informed one and no breach of fiduciary duty was sufficiently pleaded here.

Corporations -- Merger -- Parties to Whom Fiduciary Duty Owed -- Standing

6. In an action by plaintiffs, two parent corporations and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner, the corporate parents were not owed a fiduciary duty by defendant corporation under Delaware law, since the corporate parents were shareholders of the holding company, which is itself a shareholder of defendant corporation. Nor did the corporate parents have standing since they were neither purchasers nor sellers of defendant corporation's stock.

Torts -- Interference with Contractual Relations -- Sufficiency of Pleading

7. In an action by plaintiffs, two parent corporations and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner, plaintiffs have failed to sufficiently plead a cause of action for tortious interference with the performance of the holding company's contract and advantageous business relationship with its financial advisor where there is no allegation that defendant corporation intentionally procured the financial advisor's breach of its contract with the holding company, nor that the financial advisor in fact breached its contract to provide financial advice and represent the holding company in the disposition of the holding company's stock in defendant corporation.

Corporations -- Shareholders' Agreement --

88 N.Y.2d 413, *; 668 N.E.2d 1370, **;
646 N.Y.S.2d 76, ***; 1996 N.Y. LEXIS 1187

Sufficiency of Pleading for Breach of Agreement

8. In an action by plaintiffs, two parent corporations and the holding company they established to own stock in defendant corporation, arising out of the sale by defendant of all its stock in a merger with its merger partner, plaintiffs failed to sufficiently plead a cause of action for breach of a shareholders' agreement based upon defendant's obstructing or preventing the holding company from selling its stock. Plaintiffs do not allege facts sufficient to support their claim that defendant interfered with their efforts to obtain a bona fide offer for the holding company's stock. Furthermore, applying the law of New York (as provided in the agreement), plaintiffs' damages claim must fail since it is not susceptible to proof with certainty but is instead entirely speculative.

COUNSEL: *Arent Fox Kintner Plotkin & Kahn* (*George R Kucik* and *David T. Dekker* of the District of Columbia Bar, admitted *pro hac vice*, of counsel) and *Arent Fox Kintner Plotkin & Kahn*, New York City (*Jill R. Newman* of counsel), for appellants. I. The Court below erred in holding that plaintiffs' loss is not recoverable under New York's "out-of-pocket" rule of fraud damages. (*Kensington Publ. Corp. v Kable News Co., 100 AD2d 802*; *Cayuga Harvester v Allis-Chalmers Corp., 95 AD2d 5*; *Reno v Bull, 226 NY 546*; *Hotaling v Leach & Co., 247 NY 84*; *Alpert v Shea Gould Climenko & Casey, 160 AD2d 67*; *Broffe v Horton, 172 F2d 489*; *Orbit Holding Corp. v Anthony Hotel Corp., 121 AD2d 311*; *Hanlon v MacFadden Publs., 302 NY 502*; *National Conversion Corp. v Cedar Bldg. Corp., 23 NY2d 621*; *Clearview Concrete Prods. Corp. v S. Charles Gherardi, Inc., 88 AD2d 461.*) II. The Court below erred in holding that allegations of loss causation involving an alternative transaction are inherently speculative under New York law. (*Woods v Lancet, 303 NY 349*; *Shack v Holland, 89 Misc 2d 78*; *Eastwood v National Bank of Commerce, 673 F Supp 1068*; *General Rubber Co. v Benedict, 215 NY 18*; *NBT Bancorp v Fleet/Norstar Fin. Group, 159 AD2d 902*; *Brown v State of New York, 192 AD2d 936*; *Mortensen v Memorial Hosp., 105 AD2d 151*; *Greasy Spoon v Jefferson Towers, 75 NY2d 792*; *Aufrichtig v Lowell, 85 NY2d 540*; *Kenford Co. v County of Erie, 67 NY2d 257.*) III. The Court below erred by applying New York law to dismiss plaintiffs' claims without conducting a choice-of-law analysis. (*Munzer v St. Paul Fire & Mar. Ins. Co., 145 AD2d 193*; *Rosenzweig v Glen's Truck Serv., 136 AD2d 689*; *Brandman v Cross & Brown Co., 125 Misc 2d 185*; *Schultz v Boy Scouts of Am., 65 NY2d 189*; *Hart v General Motors Corp., 129 AD2d 179*; *Gray v Furia Org., 896 F Supp 144*; *Coleman v Taub, 638 F2d 628*; *Mantei v Creole Petroleum Corp., 61 AD2d 910.*) IV. The trial court erred in holding that plaintiffs Rana and Rasha lacked standing to sue, because defendants owed these plaintiffs independent duties which, when breached, injured them directly. (*Abrams v Donati, 66 NY2d 951*; *General Rubber Co. v Benedict, 215 NY 18*; *Weiss v Salamone, 116 AD2d 1009*; *Ceribelli v Elghanayan, 990 F2d 62*; *Powers v Ostreicher, 824 F Supp 372*; *Grubb v Federal Deposit Ins. Corp., 868 F2d 1151*; *Leasco Data Processing Equip. Corp. v Maxwell, 468 F2d 1326*; *Schur v Salzman, 50 AD2d 784*; *Perlman v Feldmann, 219 F2d 173, 349 US 952*; *General Elec. Co. v Bucyrus-Erie Co., 563 F Supp 970.*) V. In the alternative, plaintiffs should be granted leave to replead. (*Sanders v Schiffer, 39 NY2d 727*; *Estate of Richter v Novo Corp., 43 AD2d 1, 36 NY2d 757*; *C. E. Hooper, Inc. v Perlberg, Monness, Williams & Sidel, 72 AD2d 687*; *Cushman & Wakefield v John David, Inc., 25 AD2d 133*; *Annicaro v Structurtone, 175 AD2d 546*; *Piffath v Esposito, 58 AD2d 577*; *Rochester Poster Adv. Co. v Town of Penfield, 51 AD2d 870*; *Wattson v TMC Holdings Corp., 135 AD2d 375.*)

Skadden Arps Slate Meagher & Flom, New York City (*William P. Frank, Jeremy A. Berman* and *Daniel J. Fish* of counsel), for respondents. I. Plaintiffs' complaint does not state a cause of action for fraud or negligent misrepresentation. (*Reno v Bull, 226 NY 546*; *Mihalakis v Cabrini Med. Ctr., 151 AD2d 345, 75 NY2d 790*; *Sager v Friedman, 270 NY 472*; *Foster v Di Paolo, 236 NY 132*; *Hotaling v Leach & Co., 247 NY 84*; *Dress Shirt Sales v Hotel Martinique Assocs., 12 NY2d 339*; *AFA Protective Sys. v American Tel. & Tel. Co., 57 NY2d 912*; *Zivian v McNulty, 136 AD2d 547*; *Alpert v Shea Gould Climenko & Casey, 160 AD2d 67*; *Kensington Publ. Corp. v Kable News Co., 100 AD2d 802.*) II. Plaintiffs have failed to state a cause of action for breach of fiduciary duty under Delaware law. (*Koal Indus. Corp. v Asland, 808 F Supp 1143*; *Matter of Reading Co., 711 F2d 509*; *Coleman v Taub, 638 F2d 628*; *Dofflemyer v Hall Print. Co., 558 F Supp 372.*) III. Plaintiffs have not stated a cause of action for breach of contract. (*W.W.W. Assocs. v Giancontieri, 77 NY2d 157*; *Nichols v Nichols, 306 NY 490*; *M/A-Com Sec. Corp. v Galesi, 904 F2d 134*; *Van Valkenburgh, Nooger & Neville v Hayden Publ. Co., 30 NY2d 34, 409 US 875*; *Walther v Bank of N. Y., 772 F Supp 754*; *Sabetay v Sterling Drug, 69 NY2d 329*; *Murphy v*

American Home Prods. Corp., 58 NY2d 293; *Cross & Cross Props. v Everett Allied Co., 886 F2d 497*; *Kenford Co. v County of Erie, 67 NY2d 257*.) IV. Plaintiffs have not stated a cause of action for tortious interference with contract and advantageous business relations. (*Artwear, Inc. v Hughes, 202 AD2d 76*; *Israel v Wood Dolson Co., 1 NY2d 116*; *Ciccolo v Chicago Research & Trading Group, 161 AD2d 364*; *Guard-Life Corp. v Parker Hardware Mfg. Co., 50 NY2d 183*; *Fine v Doernberg & Co., 203 AD2d 419*; *WFB Telecommunications v NYNEX Corp., 188 AD2d 257, 81 NY2d 709*.) V. The trial court correctly dismissed causes of action asserted by Rana and Rasha for lack of standing. (*Schleidt v Stamler, 106 AD2d 264*; *Glenn v Hoteltron Sys., 74 NY2d 386*; *Torrey Delivery v Chautauqua Truck Sales & Serv., 47 AD2d 279*; *Brock v Poor, 216 NY 387*; *Ceribelli v Elghanayan, 990 F2d 62*; *General Rubber Co. v Benedict, 215 NY 18*.) VI. There is no choice-of-law issue that warrants reversal of the result below. (*First Fed. Sav. & Loan Assn. v Oppenheim, Appel, Dixon & Co., 631 F Supp 1029*; *Cooney v Osgood Mach., 81 NY2d 66*; *Neumeier v Kuehner, 31 NY2d 121*.) VII. The Court below correctly dismissed plaintiffs' claims with prejudice. (*Bardere v Zafir, 63 NY2d 850*; *Abbott v Herzfeld & Rubin, 202 AD2d 351, 83 NY2d 995*; *Licensing Dev. Group v Freedman, 184 AD2d 682*; *Hickey v National League of Professional Baseball Clubs, 169 AD2d 685*; *ATI, Inc. v Ruder & Finn, 42 NY2d 454*.)

JUDGES: Chief Judge Kaye and Judges Simons, Titone, Levine and Ciparick concur; Judge Bellacosa taking no part.

OPINION BY: SMITH

OPINION

[*418] [**1371] [***78] Smith, J.

This action arises out of the sale by defendant Smith Barney Inc. of all of its stock in a merger with Primerica Corporation. The primary issue here is whether the complaint states any cause of action entitling plaintiffs to recover a $ 33 million tax liability or any other relief. Because we agree that the complaint fails to state any cause of action, we affirm the order of the Appellate Division dismissing the complaint in its entirety.

[**1372] In 1987, defendant Smith Barney and Primerica merged, with Primerica acquiring all of the shares of Smith Barney. At the time of the merger, plaintiff Lama Holding Company owned approximately 24.9% of the shares of Smith Barney. Lama was at all times the largest single shareholder of Smith Barney. The stock purchased by Lama was designated "Rana Common Stock." Lama, incorporated under the laws of Delaware, was formed expressly to acquire and hold stock in Smith Barney for resale at a profit. Lama had purchased its interest in Smith Barney in 1982, for approximately $ 40 million, through a tritiered corporate structure. Lama was owned by two foreign entities, with 66.6% owned by Rana Investments Ltd., a British Virgin Islands corporation, and 33.3% owned by Rasha Investments, N.V., a Netherlands Antilles corporation. Rana owned 100% of Rasha, and both were part of a Middle Eastern investment group. The acquisition of Smith Barney stock by Lama was part of a complex structure created to take advantage of favorable United States tax treatment under the "General [*419] Utilities Doctrine," pursuant to which a domestic corporation could sell its assets under certain circumstances without incurring tax liability.

When Lama purchased the Smith Barney stock in 1982, it entered into a shareholders' agreement (the June 1982 agreement) whereby it agreed not to sell its Smith Barney stock for four years. Under the 1982 agreement, Lama was granted the right of first refusal on any merger, and Smith Barney's right to sell the remainder of its shares was limited. Lama decided to sell some or all of its Smith Barney stock in 1986 and, in September 1986, retained Bankers Trust Company as its financial advisor and sales representative. Plaintiffs, however, were unsuccessful in their attempt to sell any of their shares. Plaintiffs maintain that by various unlawful means, Smith Barney affirmatively tried to block, frustrate and hinder the sale of Lama's Smith Barney stock.

During 1986 and 1987 Smith Barney negotiated a merger with Primerica and, by May 1987, negotiations were apparently in their final stages. On May 19, 1987, Smith Barney's chairman and president (the individual defendants) held a meeting in London (the May 19, 1987 meeting) with representatives of Lama. Lama was informed that Smith Barney had secured a merger partner who was prepared to purchase all of Smith Barney's stock; that virtually all of the other Smith Barney shareholders were expected to vote in favor of the merger and such majority would insure consummation of the merger without the support of Lama; and that because of considerations of time and secrecy, [***79] Lama

would have to decide immediately (without the benefit of financial or legal counsel) whether it would vote its shares in favor of the merger. Lama's representatives were additionally informed that if Lama chose not to vote in favor of the merger, it would be left in an unfavorable position as a minority shareholder in a reconstituted Smith Barney. Lama, thereafter, executed a one-page agreement to vote its shares in favor of the merger and waived its right of first refusal.

Lama contends that its consent to the merger was fraudulently induced. Specifically, Lama maintains that at the May 19, 1987 meeting, defendants failed to disclose that the merger partner was Primerica, Primerica would or could withdraw from the merger if 5% of the holders of Smith Barney common stock did not approve the transaction, Smith Barney did not reveal the terms of the proxy statement which contained important tax information, and Smith Barney failed to advise [*420] Lama of the potential tax consequences of the sale of Lama's Smith Barney stock.

After executing the May 19, 1987 agreement, Lama learned that the General Utilities Doctrine had been repealed by the Tax Reform Act of 1986 and, as a result, the sale of its Smith Barney shares would constitute a taxable event. With knowledge of the likely substantial tax consequences of the merger, Lama sought to restructure Primerica's acquisition of Smith Barney's stock by having Primerica purchase Lama directly from Rana and Rasha which potentially eliminated Lama's tax liability. Primerica refused, and [**1373] the Smith Barney-Primerica merger closed in June 1987. As a result of the merger, Lama received over $ 163 million for its Smith Barney stock (a profit of approximately $ 90 million) and was subject to United States tax liability of over $ 33 million.

Lama commenced an action in Federal court against its financial advisor Bankers Trust, its legal advisor Shearman & Sterling, and the defendants herein (*Lama Holding Co. v Shearman & Sterling,*, US Dist Ct, SD NY, Duffy, J., 89 Civ. 3639 [*see, 758 F. Supp. 159*]). The Federal securities claims against the defendants were dismissed for failure to state claims, and the pendent State claims were not retained. Plaintiffs then brought this action in State court, alleging fraud and misrepresentation, breach of fiduciary duty, negligent misrepresentation, tortious interference with contract and advantageous business relations, and breach of contract. Among other things, plaintiffs seek a judgment in the amount of $ 33 million, the tax liability, a "sum to be determined at trial, for Plaintiffs' reasonably anticipated net financial gain from the disposition of The Smith Barney Investment to a third party purchaser, plus prejudgment interest," and punitive damages.

Supreme Court dismissed with prejudice plaintiffs' fraud, misrepresentation and tortious interference claims in their entirety and dismissed the breach of fiduciary duty cause of action as asserted on behalf of Rana and Rasha. The court also dismissed the breach of contract claims asserted by Rasha on standing grounds.

The Appellate Division modified and granted defendants' motion to dismiss the complaint in its entirety, holding that (1) plaintiffs could "not recover damages in fraud or negligent misrepresentation since damages under those theories are limited to indemnity for actual pecuniary loss, and do not [*421] include the greater profit that could have been made but for the false representations," (2) the claims for tortious interference with contract and prospective contract failed because no interference with contract occurred and the prospect of a contract was too speculative and, (3) assuming the truth of the allegations of breach of a fiduciary duty and breach of a contract based upon the shareholders' agreement, plaintiffs received large profits from the sale of Smith Barney stock and the claim for additional damages was speculative (*215 A.D.2d 314, 315*). This Court granted leave to appeal and we now affirm.

Fraud and Negligent Misrepresentation

Counts one and three allege fraud and negligent misrepresentation. Specifically, plaintiffs argue that defendants misled Lama's representatives at the May 19, 1987 meeting, thereby inducing their vote for the Smith Barney-Primerica merger. They claim as damages the amount of taxes they are required to pay. The issue is whether [***80] such consequential damages support the cause of action.

In an action to recover damages for fraud, the plaintiff must prove a misrepresentation or a material omission of fact which was false and known to be false by defendant, made for the purpose of inducing the other party to rely upon it, justifiable reliance of the other party on the misrepresentation or material omission, and injury (*see, Channel Master Corp. v Aluminium Ltd. Sales, 4 N.Y.2d 403, 176 N.Y.S.2d 259, 151 N.E.2d 833*; *New York*

Univ. v Continental Ins. Co., 87 N.Y.2d 308, 318, 639 N.Y.S.2d 283, 662 N.E.2d 763). "The true measure of damage is indemnity for the actual pecuniary loss sustained as the direct result of the wrong" or what is known as the "out-of-pocket" rule (*Reno v Bull, 226 N.Y. 546, 553, 124 N.E. 144*; *Hanlon v MacFadden Publ., 302 N.Y. 502, 99 N.E.2d 546*). Under this rule, the loss is computed by ascertaining the "difference between the value of the bargain which a plaintiff was induced by fraud to make and the amount or value of the consideration exacted as the price of the bargain" (*Sager v Friedman, 270 N.Y. 472, 481, 1 N.E.2d 971*). Damages are to be calculated to compensate plaintiffs for what they lost because of the fraud, not to compensate them for what they might have gained (*see, Cayuga Harvester v Allis-Chalmers Corp., 95 A.D.2d 5, 465 N.Y.S.2d 606*). Under the out-of-pocket rule, there can be no recovery of profits which would have been realized in the absence of fraud (*Foster v Di Paolo, 236 N.Y. 132, 140 N.E. 220*; *AFA Protective Sys. v American Tel. & Tel. Co., 57 N.Y.2d 912, 456 N.Y.S.2d 757, 442 N.E.2d 1268*).

[1] Accepting all of plaintiffs' factual allegations as true, there is no actionable fraud or misrepresentation. Plaintiffs' [*422] tax liability was not caused by an act or omission by defendants, but rather by the repeal of the General Utilities Doctrine under the Tax Reform Act of 1986, six months prior to the May 19, 1987 meeting. Lama's participation in the merger was a taxable event which required it to pay taxes as a result of the repeal of the General Utilities Doctrine. The complaint does not allege how defendants' failure to disclose that Primerica was the merger partner or that several directors would be treated favorably by Primerica for their votes, was fraudulent, or proximately caused the tax consequences to Lama of participating in the merger. Plaintiffs additionally fail to allege how defendants could possibly have known of Lama's ignorance of the change in the tax laws, requiring Smith Barney, as opposed to plaintiffs' own financial and legal counsel, to provide such information.

[2] Even if the claims of fraud were sufficiently alleged, plaintiffs would be limited to recovering their losses. (*Reno v Bull 226 N.Y. 546, 124 N.E. 144, supra; see also, Hotaling v Leach & Co., 247 N.Y. 84, 88, 159 N.E. 870* ["actual pecuniary loss sustained as a direct result of the wrong is the measure to be applied in fixing damages."]) There were, however, no losses here because plaintiffs, like the rest of Smith Barney's shareholders, received more than twice the fair market value for their shares.

[3] Further, the loss of an alternative contractual bargain (Primerica's purchase of Lama from Rana and Rasha rather than the purchase of stock owned by Lama) cannot serve as a basis for fraud or misrepresentation damages because the loss of the bargain was "undeterminable and speculative" (*Dress Shirt Sales v Hotel Martinique Assocs., 12 N.Y.2d 339, 344, 239 N.Y.S.2d 660, 190 N.E.2d 10*). While plaintiffs allege that but for defendants' fraud, Lama could have exercised its 25% appraisal rights to force Primerica to withdraw from the merger with Smith Barney and accept plaintiffs' offer to purchase Lama from Rana and Rasha, nowhere do plaintiffs allege that Primerica's refusal to go forward with Lama's proposal was because of defendants' fraud rather than an independent business decision made by Primerica. [**1374]

[4] Nor does the out-of-pocket rule allow for recovery of the payment of taxes, couched as consequential damages or otherwise. This case is similar to *Alpert v Shea Gould Climenko & Casey (160 A.D.2d 67, 559 N.Y.S.2d 312)*, where investors in a tax shelter sued the law firms that advised them, claiming lost profits and tax benefits they would have obtained [***81] had they invested in a viable tax shelter and not relied on their advisor's opinions. [*423] The *Alpert* Court rejected the plaintiffs' claim for the recovery of taxes, holding the recovery of taxes paid would put the plaintiffs in a better position than had they not made the choice they did. "The recovery of consequential damages naturally flowing from a fraud is limited to that which is necessary to restore a party to the position occupied before commission of the fraud" (*id., at 71*). Lama's tax payment does not naturally flow from Smith Barney's alleged fraud, but from a change in the tax laws, and recoupment by Lama of the taxes paid would put it in a better position than if it retained its Smith Barney shares.

Breach of Fiduciary Duty

Count two alleges that Smith Barney owed Lama a duty "to act in its best financial interest with the utmost good faith, with the highest degree of knowledge, skill, care, integrity, honesty, fairness and with undivided loyalty, and to comply with all other fiduciary duties." Plaintiffs maintain that Smith Barney breached its fiduciary duty to Lama by [**1375] failing to disclose to Lama, prior to issuance of the proxy material, that